















# MONOGRAPHS

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## *Cancer Research in Hispanic Populations in the United States*

1995  
Number 18

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# **Cancer Research in Hispanic Populations in the United States**

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and  
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# FOREWORD

The National Cancer Institute (NCI) is pleased to present this monograph on cancer research in Hispanic populations in the United States.

Cancer affects all Americans, but without question there are barriers to cancer prevention and treatment that exacerbate the cancer problems for Hispanic populations. For Hispanics, such factors include varied cultural patterns, language, lower economic status, and a lack of medical insurance. A paucity of Spanish-speaking health service providers complicates the situation. This monograph reports on research with a broad range of Hispanic groups in a number of places across the country. The papers compiled in this monograph will contribute to a better understanding of the diversity of the American Hispanic populations and lead the way to culturally sensitive and effective research.

NCI research has given us excellent and extensive data for some Hispanic groups, but less for others. However, the data we have provide clues to the causes of cancer as well as indications of possible methods of prevention and treatment.

This monograph is designed to add to our knowledge and not only to stimulate, but also to inform those addressing cancer in Hispanic groups. The monograph reports on research stimulated by the Hispanic Cancer Control Program (HCCP) of the NCI Division of Cancer Prevention and Control. The HCCP was created in the mid-1980s, and this monograph is visible evidence of the vitality and relevance of this program.

The great diversity in the Hispanic populations in the United States is reflected in this monograph. Cancer affects all groups but in differing ways. Differences among groups and from location to location add to our knowledge. These differences are the clues to understanding cancer, if only we know how to read them. The research in Hispanic populations reported herein will help us read these clues and lay the groundwork for future research.

I have no doubt that this monograph will benefit cancer research overall as well as specifically strengthen cancer research in Hispanic populations.

EDWARD J. SONDIK, Ph.D.  
*Acting Director*  
*National Cancer Institute*





# Introduction: Cancer Research in Hispanic Populations

Elva Ruiz, Carlos E. Caban\*

Cancer research in Hispanic populations, the fastest growing minority, is a critical undertaking that requires attention to the diversity and cultural heritage among Hispanic groups. Hispanics experience a high incidence of certain types of cancer, including cervical, stomach, prostate, gallbladder, and breast cancers. They are often underserved and understudied and may experience increases in cancer incidence, mortality, and morbidity in the future.

The purpose of this monograph is to provide key summaries of recent National Cancer Institute (NCI)-sponsored and other research findings and policy issues directed to Hispanic populations.

Hispanic health research funded by the NCI is the product of national meetings and discussions, changes within and outside the NCI, and the commitment of many researchers and others to ensure that Hispanic health research is adequate and appropriate. Cultural sensitivity is much more than just being able to speak basic Spanish. Researchers must have an appreciation of the cultural subtleties and linguistic nuances to design a study, to be able to work with Hispanic subjects and communities, and to be competent to interpret findings appropriately. The studies in this monograph emphasize the cultural and linguistic requirements necessary for culturally competent research and represent excellent models for cancer research in Hispanic populations.

## Recent Milestones Affecting Hispanic Health Research

In the past 10 years, there has been continuous growth in activities related to Hispanic health research and policy, as summarized by the publications noted in Table 1. Although not

comprehensive, this list provides documentation of the growing national importance of addressing the needs of Hispanics.

At the federal level, the U.S. Department of Health and Human Services (DHHS) 1985 "Report of the Secretary's Task Force on Black and Minority Health" (1) summarized the gaps in data concerning minorities, including Hispanics, and the need to address the problems. This report led to the 1990 National Institutes of Health (NIH) policies on inclusion of minorities and women in study populations (2), which required inclusion of minorities, such as Hispanics, in NIH-supported research. As a result of action by the U.S. Congress, the 1993 NIH Reauthorization Act required that women and minorities be included in clinical research, resulting in publication of the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" (3) in March 1994. During this period, a major thrust of the Surgeon General resulted in the 1993 Surgeon General's National Hispanic/Latino Health Initiative (4). Follow-up activities are under way in these areas.

The scientific literature has grown with individual publications by researchers and with special publications highlighting Hispanic research. The latter includes the 1990 *American Journal of Public Health* Supplement "Hispanic Health and Nutrition Examination Survey, 1982-1984: Findings on Health Status and Health Care Needs" (5) and a special issue of the *Journal of the American Medical Association*, January 9, 1991, which featured papers on Hispanic research (6). Recently, a major bibliography, "Hispanic-American Health: January 1990 Through July 1994" was published as part of the *Current Bibliographies in Medicine* by the National Library of Medicine, the NIH (7). This bibliography includes 1799 citations. Finally, the American Public Health Association recently published "Latino Health in the US: a Growing Challenge," which discusses and summarizes issues and data on Hispanic subgroups (8).

## Research Initiatives of the NCI Hispanic Cancer Control Program

Responding to the need to address Hispanic health issues, as identified in the 1985 DHHS report, the NCI established the

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See "Note" section following "References."

Table 1. Selected recent milestones affecting Hispanic health research	
Year	Milestone
1985	DHHS "Report of the Secretary's Task Force on Black and Minority Health" (1)
1990	NIH/ADAMHA policies on inclusion of minorities and women in study populations (2)
1990	"Hispanic Health and Nutrition Examination Survey, 1982-1984: Findings on Health Status and Health Care Needs" (5)
1991	Special issue on Hispanic research (6)
1993	Surgeon General's National Hispanic/Latino Health Initiative (4)
1994	"NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" (3)
1994	"Hispanic-American Health: January 1990 Through July 1994," National Library of Medicine (7)
1994	"Latino Health in the US: a Growing Challenge" (8)

Hispanic Cancer Control Program in 1987 in the Division of Cancer Prevention and Control. Hispanic investigators were recommended for advisory and peer-review committees, and Hispanic representation was added to the Board of Scientific Counselors of the Division of Cancer Prevention and Control of the NCI.

Under the direction of Elva Ruiz, the director of the Hispanic Cancer Control Program, various initiatives were undertaken (Table 2). Three working groups were organized and included both Hispanic and non-Hispanic health experts working with Cuban-American, Mexican-American, and Puerto Rican communities. The working group meeting reports of the Hispanic Cancer Control Program began to set a research agenda with recommendations that resulted in the first NCI Request for Applications (RFA) specifically targeting Hispanic health needs. This RFA, issued in 1989, culminated in the funding of five intervention research projects targeting Hispanic Americans at Arizona State University, the University of Colorado, the University of California at Irvine, the University of California at San Diego, and The University of Texas Health Sciences Center at Houston. Many types of research activities tailored to the Hispanic community included ethnographic surveys, attention to cultural issues, church-based community interventions, longitudinal breast/cervical cancer studies, investigations related to community health promotion, use of trained volunteers, coalition building, and consumer education. These studies constitute the core of the investigations discussed in this monograph.

To maintain contact with the Hispanic scientific community and to obtain relevant and current input, a National Hispanic Cancer Control Research Network (NHCCRN) was established in 1990. Its primary objectives were to increase the pool of Hispanic cancer research investigators and to improve communication and information exchange. To date, more than 200 researchers have been identified across the nation and in Puerto Rico. These researchers include epidemiologists, physician investigators, social psychologists, statisticians, and scientists from a dozen other disciplines.

In 1991, the NCI supported the North American Conference on Cancer in Hispanics, held in September 1991 at the Arizona

Cancer Center, the University of Arizona, in Tucson. More than 400 participants attended.

Efforts were also begun to provide technical assistance to Hispanic researchers who were interested in NIH support. In conjunction with the Tucson conference, the NHCCRN sponsored a grant-writing and grant-review workshop for 25 potential Hispanic investigators. The following spring, the NHCCRN carried the grant-writing workshop one step further by conducting a mock review of bona fide applications prepared by workshop participants and reviewed by volunteer NCI peer-review panel members. This two-phase NHCCRN activity resulted in a group of investigators forming a consortium and subsequently developing a grant application that was funded for \$1.5 million per year for 5 years.

As a byproduct of the grant-writing workshop, NHCCRN produced in 1992 the *Quick Guide for the Preparation of Grant Applications* (9), a booklet that helps investigators find their way through the sometimes confusing process of preparing an application for an NIH grant. This booklet proved to be so useful that it was adopted by other NCI programs, as well as by other institutes at the NIH. In addition, the guide has been frequently requested by cancer centers, universities, and other Public Health Service agencies. Thus, the benefits of the guide extend well beyond technical assistance to Hispanic scientists.

To further stimulate the national effort to address the needs of Hispanics, the National Hispanic Leadership Initiative on Cancer (NHLIC) was established through a 1992 RFA announcement, resulting in two awards. The NHLIC is designed to 1) focus the attention of national, state, and local leaders on Hispanic cancer control issues; 2) build coalitions in Hispanic communities; 3) enhance data collection and research; 4) reduce cancer risk behaviors; and 5) evaluate Hispanic outreach programs. Although the projects funded under the NHLIC Cooperative Agreement had been in operation only 2 years, the NHLIC-En Acción Project was able to present preliminary focus group and base-line data findings at the 1994 American Public Health Association national meeting held in Washington, D.C., on October 30 through November 3.

## Organization of the Monograph

This monograph presents the findings of various NCI-supported Hispanic cancer research projects and other cancer-related research programs targeting Hispanics in the United States. It highlights what effective programs require when targeting Hispanics and distills key aspects of each model or study to provide approaches that are novel, interdisciplinary, culturally sensitive, and effective.

The monograph is organized into five sections. These sections represent a course for progressive intervention research design development, address the goals of the Healthy People 2000 for Hispanics, and foster the empowerment of the Hispanic community to engage in active cancer control efforts.

The first section, entitled "Demographics," provides a detailed profile of the diversity of the Hispanic population and examines the impact of this diversity on the cancer experience of the Hispanic population. In addition, it addresses such issues as the use of Spanish surnames to identify Latinos.

Table 2. Progress in Hispanic cancer prevention and control initiatives: 1987-1995

Year	Initiative
1987	The NCI establishes the Hispanic Cancer Control Program
1988	Three working groups assess needs
1989	RFA for Hispanic intervention research
1990	National Hispanic Cancer Control Research Network established
1991	North American Conference on Cancer in Hispanics
1991	Grantsmanship Workshop for Hispanic Investigators
1992	<i>Quick Guide for the Preparation of Grant Applications</i>
1992	RFA for National Hispanic Leadership Initiative on Cancer (NHLIC)
1993	Preliminary findings of Hispanic intervention research projects presented at the national meeting of the American Public Health Association in special session
1994	Grantsmanship Workshop for Hispanic Investigators
1994	NHLIC preliminary findings presented at the national meeting of the American Public Health Association in special session
1995	Cancer Research in Hispanic Populations, NCI monograph



The second section is a comprehensive overview of the epidemiology of cancer among Hispanics. It discusses the importance of sources of data (or lack of sources) and implications for future research and policies. Included in this section are comparison data on breast cancer screening from various studies as well as a case-control study of ethnic differences in mutagen sensitivity to lung cancer among Mexican-Americans.

The third section focuses on understanding behavioral, cultural, and ethnic issues as they influence risk factors and health practices of Hispanics. Two acculturation scales associated with cancer-screening practices of Mexican-Americans are compared. Findings on knowledge, beliefs, and health practices of urban Hispanic women and Latino males' attitudes and behaviors affecting their partner's cancer-screening behavior are reported. In addition, the section includes data on the psychosocial correlates of smoking among Latina adolescents and examines the attitudes and behaviors of health care professionals toward screening for breast and cervical cancers in Hispanic women.

The fourth section features intervention studies ranging from an ethnography survey designed for breast and cervical cancer control intervention research among Latinas to a variety of community-based cancer prevention and control interventions. These studies provide an overview of the characteristics and relationships of culturally appropriate and community-accepted, cancer-related interventions. Findings include the merits of church participation, the use of *promotoras* (community volunteers) in cancer-screening programs, the relative success of using natural social networks to recruit and retain Hispanics in research studies, and the strategies required to generate behavior modification among Hispanic American women's health practices as well as programmatic strategies required to sustain long-term effectiveness.

The final section focuses on the future and discusses the new NIH guidelines on inclusion of women and minorities in clinical research and the implications for expanded cancer research in Hispanic Americans. This final paper describes advances made at the NIH/NCI but points out that there still remain significant untapped opportunities for research targeting Hispanics and for using findings to guide future research. Continued research and application of findings are vital if the Healthy People 2000 goals for Hispanic Americans are to be met and if research methodologies that are now emerging to help protect the Hispanic peoples are to help others, regardless of race, ethnicity, or gender.

## Concluding Remarks

Through its creation and support of the Hispanic Cancer Control Program, the NCI has stimulated substantial Hispanic can-

cer research during the last 7 years. This monograph chronicles the important findings emerging from those investigations. Clearly, Hispanic Americans have gained important ground since 1985; the NCI has begun to acknowledge the needs of Hispanics, and significant and crucial first steps have been taken to understand and reduce cancer risks through increased research on Hispanic populations. However, research involving Hispanics has far to go to catch up with research involving other groups, including African-Americans and white Americans.

Thus, it is timely to publish a monograph that demonstrates the uniqueness of the Hispanic intervention research; it documents methodologies, processes, and outcomes and provides a ready document for information dissemination to the scientific community and to a wide audience of administrators and policy makers.

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## Note

An Executive Committee was established to provide guidance on the development of the monograph and to ensure its breadth and scientific merit. Members of this committee included Amelie Ramirez, Alberto Mata, Alfred McAlister, Estevan Flores, Felipe Castro, Allan Hubbell, Ana Navarro, Edward Trapido, Robert Kaplan, and Elva Ruiz. The Executive Committee and the following individuals—Fernando Trevino, Robert Valdez, and Lucina Suarez—graciously contributed their time and expertise under an exceedingly compressed time frame of 3 months to ensure the quality of the monograph through their careful and thoughtful reviews of the manuscripts during developmental stages. We gratefully acknowledge their substantial contributions.





# The Emerging Hispanic Population: a Foundation for Cancer Prevention and Control

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Although making up only 9% of the U.S. population and concentrated in urban areas of a few states, Hispanics are found throughout the country and represent a mix of historical and cultural backgrounds. This diverse group cuts across racial and ethnic lines, with origins in various countries of Europe and North, Central, and South America. The Hispanic population has several distinguishing demographic characteristics, including its rapid growth rate, relative youth, and low educational and socioeconomic levels. However, considerable differences exist among Hispanic groups, particularly in median age, household size, education, and family income. The majority of Hispanics face barriers to health care access, including a lack of health insurance coverage, underrepresentation in health care fields, and cultural and language differences. These distinct demographic characteristics and barriers have a direct impact on the risk of cancer in Hispanics and on the development of prevention and control strategies. The purpose of this review is to examine the demographic and socioeconomic characteristics of Hispanics and issues of access to health care among this population within the context of cancer prevention and control. [Monogr Natl Cancer Inst 18:1-9, 1995]

Although the term "Hispanic" was first used to describe persons of Spanish origin more than 2000 years ago, the label gained official acceptance only in recent decades. The federal Office of Management and Budget introduced the term in the 1970s (1), and the U.S. Bureau of the Census first identified persons of "Spanish/Hispanic" origin in 1980. Before 1970, the term rarely appeared in U.S. statistics or in public discourse. Health data on other minority populations, particularly blacks and Asians, have been collected for decades, but compilation of information about Hispanic Americans is fairly recent (2). Currently, the census tabulates demographic information on the 24 million-plus Americans (3) under the broad "Hispanic" umbrella: persons of Mexican, Puerto Rican, Cuban, Central and South American, and "other Hispanic" origin, including Spaniards and Dominicans.

Implied in the Hispanic classification is the existence of commonality in traits, characteristics, and background. To the extent that members of this population trace their roots to one of the

Latin American countries or to the European peninsula that became Spain and Portugal, this is true. The implicit homogeneity of Hispanic Americans, however, is dispelled by the notable differences among the various Hispanic groups. Hispanics belong to all races—white as well as black, Asian, and Native American. Indeed, the Hispanic population reflects diversity not only in race, but also in nationality, ethnicity, culture, religion, socioeconomic status, and social class.

This review examines the demographic and socioeconomic characteristics of Hispanics and issues of access to health care among this population within the context of cancer prevention and control.

## Historical Perspective

Origins of the Hispanic Americans can be traced to southwestern Europe's Iberian Peninsula, named for the prehistoric Iberian people. Ancient cultures, seeking trade and conquest, contributed to the racial mix of latter-day Spaniards. These cultures included Romans, Germans, Celts, and Jews. Among the strongest influences was that of the Muslims, whose centuries of rule over Spain drew to a close in the late 1400s, ushering in the Christian Era.

During the early period of exploration in the New World, throughout the 16th century, the Spanish were a dominant force. Conquistadors and missionaries were the major players in an exhaustive pursuit of treasure and territory. They encountered and gained control over native populations of what is now the southwestern United States, Mexico, Central and South America, and the Caribbean Islands. To ensure domination of the peoples inhabiting this new land, mixed marriages were encouraged. As a result of extensive racial interaction, modern-day Hispanic

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See "Notes" section following "References."



Americans represent a blend of diverse civilizations, including those of the Mayans, Incas, Aztecs, Toltecs, Caribs, and other Native Americans.

The Spaniards' entry into the New World began in 1492 in what are now the islands of the Bahamas, Española (Dominican Republic), and Cuba and began a year later in Puerto Rico. All these lands were discovered by Christopher Columbus, as was the continent of South America on his third voyage, when he reached the coast of Venezuela in 1498. In ensuing years, Spanish culture was introduced throughout Central and South America, Mexico, and the southern United States. The oldest settlement under the American flag is San Juan in Puerto Rico (settled in 1521), where the island natives and, later, imported West Africans were bound into slavery (4). A decade earlier, the Spaniards were founding settlements in Cuba, where African slave labor also was introduced.

The early European explorers introduced diseases, such as smallpox, that decimated indigenous populations in numerous parts of the New World. As a result of this large-scale population decrease, the ensuing migration of the Spanish and other Europeans made it likely that a major portion of the current gene pool in particular areas would be composed of Caucasoid genes.<sup>1</sup> For example, of Mexican-origin peoples who have immigrated to south Texas, 61% of the gene pool is Caucasoid, 31% is Amerindian, and 8% is Negroid. Also, the admixture of Amerindian genes in Puerto Ricans and Cuban-Americans is considerably lower than the proportion of genes derived from West Africans.<sup>1</sup>

By the mid-16th century, Spanish exploration had crossed the territory that would become the southern United States, from Florida to the Gulf of California. Efforts on another front had brought the Aztec, or Mexica, civilization under the Spanish crown. By the 1780s, more than half of the present United States was under Spanish control. The purchase of the Louisiana Territory from France in 1803 gave U.S. citizenship to thousands of the region's inhabitants, including Hispanics.

In Mexico, the Spanish Colonial Period lasted 300 years, until independence was fought for and won in 1821. The portion of Mexico that was to become Texas gained sovereignty and eventual admission to the Union. Today, Hispanics in Texas number more than 4 million, or more than one fourth of the state's population; of these, 90% are of Mexican origin.

In 1848, the Treaty of Guadalupe Hidalgo allowed the United States to absorb the northern regions of Mexico, consisting of California, New Mexico, Arizona, and parts of Nevada, Colorado, Utah, and Wyoming. The acquisitions resulted in American citizenship for more than 80 000 Mexicans (5). At the end of the 19th century, Spanish control in the New World diminished further, when Cuba gained independence. After the Spanish-American War, many Cubans migrated to the United States. As a further result of that war, the United States took control of Puerto Rico from Spain and, in 1917, granted U.S. citizenship to all Puerto Ricans.

To flee from poverty and their country's political and economic instability, many immigrants from Mexico crossed into the United States during the early 20th century (4). Traced from Mexico's revolution of 1910, immigration, both legal and illegal, continues on a large scale. Braseros, or temporary

workers, came to the United States in the period 1942-1964, and many stayed.

Similarly, the promise of prosperity has attracted large numbers of Puerto Ricans and Cubans over the years. The Communist takeover of Cuba in 1959 resulted in a dramatic flight to freedom, and most Cuban immigrants settled in Florida's Miami area. Political instability in Central and South American nations during the 1980s also produced a large influx into the United States (6,7). Today, political and economic turmoil in Cuba spawns a steady stream of new immigrants. An agreement with the Cuban government in 1994 will allow 20 000 immigrants from that country into the United States each year.

Although attention is focused on the rising number of Hispanic immigrants, almost two thirds of all Hispanic Americans were born in the United States (3). Nearly three quarters are native-born or naturalized citizens. About 67% of Mexican-Americans were born in this country, and another 7.5% became citizens after arrival here. Among Cuban-Americans, 64% are native-born or naturalized compared with 46% of South Americans and 36% of Central Americans. A large proportion of Central Americans immigrated during the 1980s, thus not living in the United States long enough to complete the naturalization process (3).

## Geographic Distribution

Hispanics are found in all 50 states, but the vast majority (84%) reside in eight states (Fig. 1) (8). More than half live in California and Texas and are primarily Mexican in origin. Another 33% of the total Hispanic population are divided among New York, Florida, Illinois, New Jersey, Arizona, New Mexico, Colorado, and Massachusetts. Among states in which Hispanics constitute the highest percentage of the state's populations, New Mexico ranks at the top. Nearly four of every 10 New Mexicans are of Hispanic origin. In California and Texas, that figure is one in four. Hispanics make up more than 10% of the population in eight states, including Arizona (18.8%), Colorado (12.9%), New York (12.3%), Florida (12.2%), and Nevada (10.4%). Mexican-Americans are concentrated in the Southwest and Midwest, Cuban-Americans in the Southeast (primarily in Florida), and Puerto Ricans in the Northeast.

More Hispanic Americans (90.4%) live in metropolitan areas (8) than non-Hispanics (76.2%). More than half of all Hispanics reside in central cities, compared with 30% of non-Hispanics. The largest single concentration of Hispanics, almost 5 million, is found in the Los Angeles Consolidated Metropolitan Statistical Area (CMSA). Fig. 1 shows the Hispanic totals in the Los Angeles CMSA, New York CMSA (almost 3 million), and 10 other metropolitan areas.

When planning health programs, it is important to take into consideration the geographic distribution of the Hispanic population. This distribution reflects waves of immigration representing differences in education, socioeconomic backgrounds, and employment. Such differences in personal characteristics may in turn have an impact on cancer incidence, which may vary among the different Hispanic populations and their geographic distribution (9).



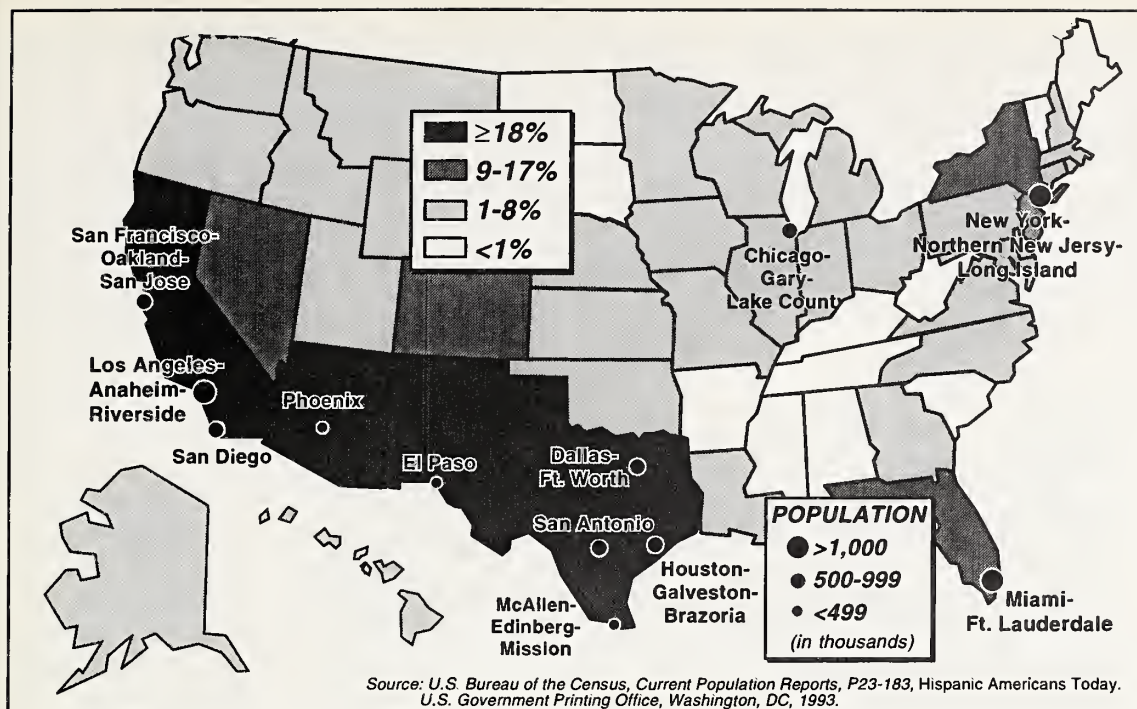


Fig. 1. Percent Hispanic of total population, by state, with selected metropolitan areas.

## Demographic Data and Trends

The Hispanic population has several distinguishing demographic features. High rates of immigration and fertility place the Hispanic population among the fastest growing segments in the United States and make this the youngest ethnic group in the country. In education and economic status, Hispanics lag behind other populations. Demographers forecast continued fast growth and low educational and income levels among Hispanics (10,11).

From 1950 to 1980, the Hispanic population ballooned by 265%, compared with a growth increase of 50% for the total

U.S. population (12). From 1980 through 1990, the Hispanic proportion of the U.S. total grew from 6.4% to 9% (8). During the 1980s, almost 40% of all immigration to the United States was from Latin America (13). The most dramatic increases were in California, where the Hispanic percentage of the state's population rose 6.6%. Within the next few years, the proportion will likely approach 40% of the state's total (14).

With a population of more than 13 million, Mexican-Americans make up more than 60% of the Hispanic total. Puerto Ricans constitute the second largest Hispanic group (about 12%), followed by Central Americans, Cuban-Americans, and South Americans (Fig. 2).

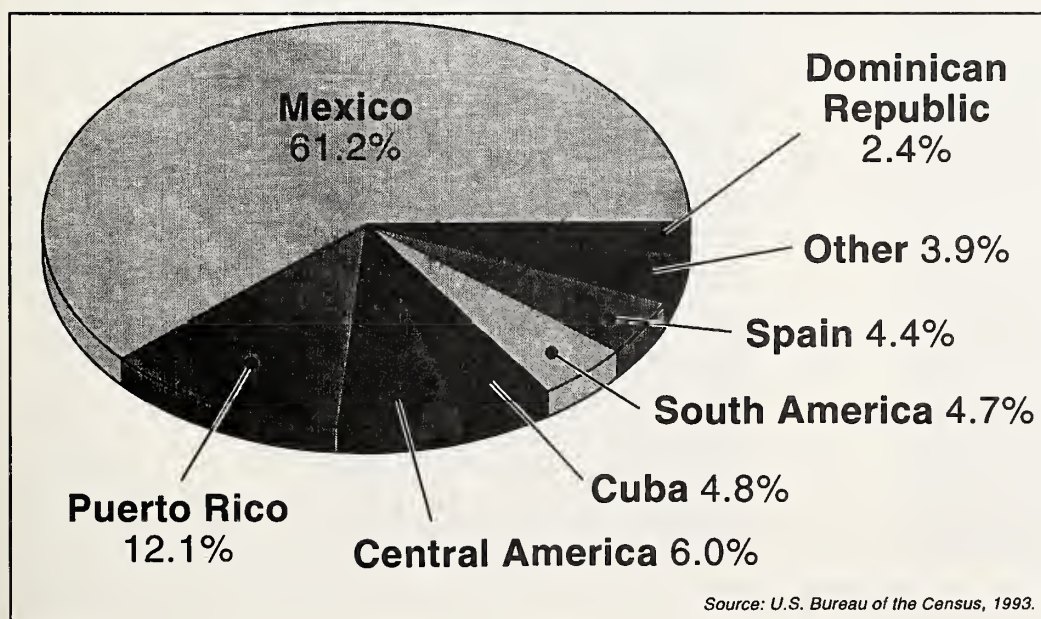


Fig. 2. U.S. Hispanic populations by origin.



These proportions reflect overall Hispanic growth rates of 61% during the 1970s and 53% in the 1980s (Fig. 3). Contributing significantly to this growth was the large increase in Mexican-Americans (93%) from 1970 to 1980; this proportion dropped to 54% from 1980 to 1990. High growth was also seen in Hispanics from Central and South America, whose numbers grew by 67% during the 1980s.

By the end of this decade, the U.S. Hispanic population is projected to exceed 30 million, making it the largest ethnic population in the country. By the year 2030, the number of

Hispanics is expected to double and to constitute about 17% of the U.S. population (8).

### Age, Education, and Income

The Hispanic population is young (Fig. 4). About 60% of all Hispanics are under 30 years of age, as opposed to 44% of non-Hispanic whites. The proportion of non-Hispanic whites older than age 55 (22%) is twice as high as that of Hispanics.

In 1990, the median age among Hispanics was 26.2 years (15), 8 years younger than non-Hispanic whites (16). Mexican-

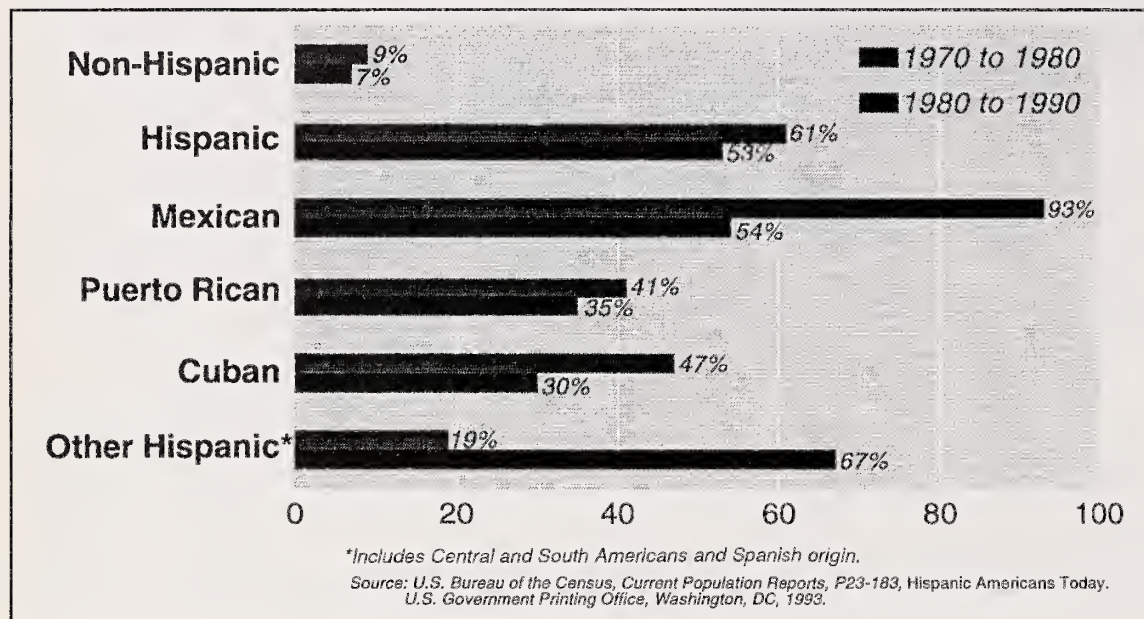


Fig. 3. Percent Hispanic population growth by origin, 1970-1990.

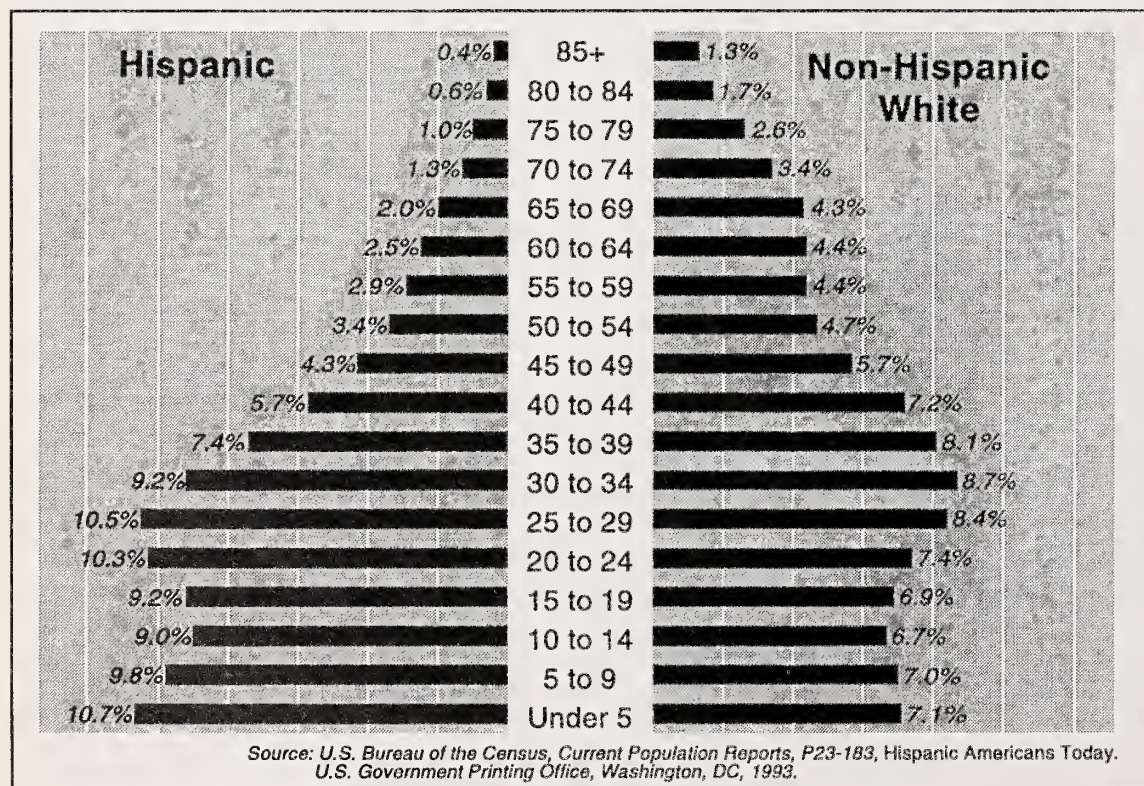


Fig. 4. Age of the Hispanic population compared with that of the non-Hispanic white population.



Americans (median age, 24.3 years) represented the youngest population, compared with 26.7 years for Puerto Ricans, 27.9 years for Central and South Americans, 39.3 years for Cuban-Americans, and 31.0 years for other Hispanics (15).

In the analysis of youth growth trends, long-term projections foresee a threefold increase in Hispanics under age 18 nationwide from 1982 to 2020 (17). Over the same time span, the non-Hispanic white youth population is expected to drop 13%. It is projected that, by the year 2020, one in four youths in this country will be Hispanic.

While the Hispanic youths increase in number, the same is true among older members of the population. Hispanics represent the fastest growing segment of the elderly population in the United States. The proportion of older Hispanics, however, is still relatively small, according to 1990 census data (15). About 5% of Hispanics were 65 years old or older, compared with 13% of non-Hispanics. Among the subgroups, the highest percentage of persons in this age category was found among Cuban-Americans (about 15%). Only 3% of Central Americans and South Americans, 4.4% of Mexican-Americans, and 4.7% of Puerto Ricans were 65 years old or older (15).

Although educational levels among Hispanics have improved in recent years, a wide gap remains between Hispanics and non-Hispanics (Table 1). Less than half of all Hispanics aged 25 years or older have completed high school, compared with about 77% of non-Hispanics (15).

Educational problems are most acute among Mexican-Americans, with only a 38.8% high school graduation rate. Education rates of other Hispanic groups are better, although still below those of non-Hispanics. High school graduation levels are 50.5% for Puerto Ricans, 55.8% for Cuban-Americans, 59.1% for Central and South Americans, and 67.2% for other Hispanics (15). Almost 10% of Hispanic adults have 4 or more years of college; this is less than half the proportion for non-Hispanics (21.3%). Mexican-Americans represent the lower end of the spectrum as well, with 5.4%, compared with 17.9% of Cuban-Americans, 15.9% of Central and South Americans, 9.3% of Puerto Ricans, and 16% of other Hispanics (15).

The difference in income levels between Hispanics and non-Hispanic whites is considerable (Table 1). Hispanic men have the highest labor force participation rate among all male popula-

tion groups, yet more than one fourth of Hispanics live in poverty, and the median annual family income is about \$22 000 (15). These figures contrast sharply with those for non-Hispanic whites: 9.5% of families living in poverty and a median annual household income of about \$32 000 (18). The poverty rate is highest for Puerto Rican families (37.5%) and lowest for Cuban-Americans (13.8%). Although the percentage of male and female civilians in the U.S. labor force is approximately the same for Hispanics and non-Hispanics, the unemployment rate for persons aged 16 years or older is higher for Hispanics (10%) than for non-Hispanics (6.9%) (15).

## Family Characteristics and Language

During the past 30 years, the average size of Hispanic households has decreased (19). The mean number of persons per family among Hispanic homes is 3.8 versus 3.1 for non-Hispanic whites (17) (Table 2). In contrast, the average for Cuban-Americans is 2.8 (9). The overall Hispanic mean is driven higher by Mexican-Americans (4.1 persons per family). In all, about 29% of Hispanic families have five or more members, compared with 13% of non-Hispanic families (15).

Recent research (19) and census data challenge the presumption long held by many that Hispanic families are more stable than non-Hispanic families. A study of 1980 census results reported higher rates of marital disruption (divorce and separation) for Puerto Ricans than for non-Hispanic whites, with only negligible differences in levels among Mexican-Americans, Cuban-Americans, and non-Hispanic whites (20). Among Mexican-Americans and Cuban-Americans, research suggests that levels of educational attainment and marital instability show a correlation, while the reverse is true among Puerto Ricans (21).

Consequently, the percentage of households headed by females with no spouse present is significantly higher among Hispanics than among non-Hispanic whites (24% versus 14%). Among Hispanic groups, Puerto Ricans have the highest percentage of female heads of household, and Mexican-American households have the lowest (Table 2). Almost one in two Hispanic families headed by females alone is living below the poverty level, compared with about 32% of non-Hispanics. The situation is even more dire among Puerto Ricans, whose poverty

**Table 1.** Percent education/income/labor force of Hispanics compared with non-Hispanic whites

	Non-Hispanic white	All Hispanics	Mexican- American	Puerto Rican	Cuban- American	Central and South American	Other Hispanic origin
<b>Education</b>							
<5 y of school*	2.0	15.9	21.0	11.0	9.8	10.1	7.2
≥4 y of high school	77.4	47.4	38.8	50.5	55.8	59.1	67.2
≥4 y of college	21.3	9.5	5.4	9.3	17.9	15.9	16.0
<b>Income</b>							
Families below poverty level, %	9.5	25.0	25.0	37.5	13.8	22.2	19.4
Median income	\$31 945†	\$22 330*	\$22 439*	\$16 169*	\$25 900*	\$23 568*	\$25 635*
<b>Labor force participation‡</b>	65.5	65.4	65.6	52.8	64.1	70.3	64.5

\*Source: U.S. Bureau of the Census, Current Population Reports: The Hispanic Population in the United States: March 1991. Series P-20, No. 455, Washington, D.C.: U.S. Govt. Print. Off., 1991.

†Source: U.S. Bureau of the Census, Current Population Survey, March 1991.

‡Source: Statistical Record of Hispanic Americans, 1993.



**Table 2.** Family characteristics of Hispanics compared with non-Hispanic whites

	Non-Hispanic white	All Hispanics	Mexican-American	Puerto Rican	Cuban-American	Central and South American	Other Hispanic origin
Average family size*	3.13	3.8	4.06	3.37	2.81	3.81	3.38
Married couple with family, %*	79.4	69.3	73.5	52.4	76.1	66.1	65.2
Female head of household (no spouse), %†	14	23.8	19.1	43.3	19.4	26.1	27.5
Speak Spanish at home, %‡	0	82.9	68.0	70.5	85.0	89.8	85.4

\*Source: U.S. Bureau of the Census, Current Population Reports: The Hispanic Population in the United States: March 1991. Series P-20, No. 455, Washington, D.C.: U.S. Govt. Print. Off., 1991.

†Source: U.S. Department of Health and Human Services, Surgeon General's National Workshop in Hispanic/Latino Health: Public Health Regions VI and VII, San Antonio, Tex., March 22-23, 1993.

‡Source: Statistical Record of Hispanic-Americans, 1993.

rate is about 64% for families in which females head the household (15).

Eight in 10 Hispanic persons speak Spanish rather than English at home (3) (Table 2). The largest proportion who speak Spanish at home was found among Central and South Americans, with about 90% in that category. In addition, about 85% of Cuban-Americans and persons of other Hispanic origin said they preferred to speak Spanish at home.

## Access to Health Care

For various reasons, Hispanics have limited access to regular health care. A large percentage of Hispanics are uninsured (Table 3). Many seek health care in public facilities, such as hospital emergency rooms, which are overloaded and overextended. The shortage of both Hispanic health care providers and Spanish-speaking and culturally sensitive health professionals is acute. In addition, language and cultural differences present barriers for many families.

As noted earlier, most Hispanics are concentrated in urban areas in which hospitals, clinics, and other health facilities are located. However, they are not receiving care that is early, adequate, or comprehensive. Hispanics also underutilize preventive services, including breast examinations, Pap smears, and blood pressure checks. Because of these and other factors, Hispanics are at greater risk for serious health problems and present with advanced diseases and complications (22).

Lack of private and public insurance is a critical factor for millions of Hispanics. Many Hispanics are among the "working poor," who receive no employer-subsidized health insurance. In other instances, they have access to group insurance but cannot

afford the premiums to cover themselves and their families. While 13% of non-Hispanic whites are uninsured, one third of the Hispanic population falls into this category. The figures are even higher for Mexican-Americans (36% uninsured) and Central and South Americans (40%), while about 24% of Cuban-Americans lack insurance. Only 14% of Puerto Ricans are uninsured because of the high proportion of families receiving Medicaid (35%) (23). Uninsured Hispanics are less likely to 1) have a regular source of health care, 2) have visited a physician in the past year, 3) have received a routine physical examination, and 4) rate their health status as excellent or very good (24).

More than one fourth of the country's Hispanics are eligible for Medicaid, yet in 1991 only 17% received this assistance (22). This situation can be attributed partially to the fact that states with high concentrations of Hispanics typically exercise stringent eligibility criteria. In addition, as former Surgeon General Novello noted, "In a culture dominated by honor and pride, there is a pervasive fear of getting involved in a health care system where the language is not understood, where the forms are too long and where the people behind the windows may seem to be judging more than caring" (22).

The impact of many access indicators, such as lack of health insurance coverage, lack of linkage with regular sources of health care, and other system-related and socio-cultural barriers, hinders a large proportion of Hispanics from gaining early access to cancer prevention, diagnosis, and treatment.

Underrepresentation of Hispanics in health-related fields is also a major issue. The 1990 Hispanic population constituted 9% of the nation's total; however, less than 5% of all U.S. physicians and only 5.6% of all first-year students enrolled in

**Table 3.** Percent insurance coverage of Hispanics compared with non-Hispanic whites\*

Insurance	Coverage, %						
	Non-Hispanic white	All Hispanics	Mexican-American	Puerto Rican	Cuban-American	Central and South American	Other Hispanic origin
Private	77	48	45	42	53	46	57
Medicaid	7	18	13	35	8	10	13
Medicare	14	6	4	6	14	3	7
Uninsured	13	32	36	14	24	40	21

\*Source: Labor Council for Latin American Advancement and National Council of La Raza, Hispanics and Health Insurance Vol 1: Status. March 1992.

U.S. medical schools were Hispanic. Mexican-Americans, who make up almost two thirds of the Hispanic population, account for only 1.7% of total medical school enrollment. In addition, the proportion of Hispanics in the fields of dentistry, nursing, and pharmacy is between 2.5% and 3.5% (25).

## Class and Race Issues

A basis for understanding the Hispanic population's limited access to health care can be found in its general socioeconomic class standing. Indeed, class issues affect access to care not only for Hispanics, but also for all Americans. For example, "the mortality rate for heart disease in blue-collar workers (operators) was 2.3 times higher than the rate in managers and professionals" (26). Being born into a family with a lower level of education, occupational standing, and income often limits one's life chances and access to the goods of society throughout the life cycle (27). Particularly harmful are effects of a high high school dropout rate among Hispanic youth. The "pipeline effect" ultimately results in small proportions of Hispanic college graduates and even lower percentages of college graduates in the health care professions.

Racial factors also act as barriers to health care. User-friendly, culturally sensitive, and responsive health care systems have not yet been fully conceptualized, developed, and diffused to present patients with personal and caring interactions in a familiar language. Cultural competency training for health care personnel can help combat racist, discriminatory actions and attitudes based on stereotypes and ignorance of important cultural attributes (28,29).

## Cancer Mortality Rates

Collection and tabulation of health data regarding Hispanics are inadequate. Hispanics are more prone to diseases such as diabetes, tuberculosis, and acquired immunodeficiency syndrome than non-Hispanic whites (9). However, although heart disease and cancer are the two leading causes of death for

Hispanics, their rates are lower than those for non-Hispanic whites (9).

National mortality statistics from 1986 to 1988 showed lower cancer death rates among Hispanics than among non-Hispanic whites (30). For lung cancer, the age-adjusted death rate per 100 000 population in Hispanics was 36.3 for men and 11.9 for women, as opposed to 80.7 in non-Hispanic white males and 32.1 in non-Hispanic white females. Breast cancer mortality rates among women were 16.6 for Hispanics and 30.7 for non-Hispanic whites. Colorectal cancer death rates were 13.6 for Hispanic men and 27.9 for non-Hispanic white men and 8.9 for Hispanic women and 19.4 for non-Hispanic white women. The death rate from cervical cancer, however, was higher among Hispanic women (4.7) than among non-Hispanic whites (2.7).

In a study of selected geographic sites for the National Hispanic Leadership Initiative on Cancer: *En Acción*, rates of mortality from various cancers were collected. Statistics reflected death rates among Mexican-Americans in San Antonio and Brownsville, Tex., as well as among Mexican- and Central Americans in San Francisco and San Diego, Calif. Comparative figures for other cities in the study were not available because of differences in data-collection techniques.

Statistical analysis from the four Texas and California metropolitan areas showed an overall lower death rate from cancer of all anatomic sites among Mexican-Americans and Central Americans in comparison to their non-Hispanic white counterparts.<sup>2</sup> Differentials in death rates for men and women varied among geographic areas. Table 4 shows rate ratios of age-adjusted death rates from leading cancers for Hispanics compared with non-Hispanic whites. Cancer mortality among Hispanics compared with that among non-Hispanic whites was 40%-50% lower in San Francisco, 30% lower in San Diego, and 20% lower in San Antonio and Brownsville. Much of the difference can be attributed to lower death rates from cancers of the lung, breast, prostate, colon, esophagus, urinary bladder, and oral cavity. For example, lung cancer mortality rates in all four cities were more than 60% lower among Hispanic women and 40%-60% lower among Hispanic men. Comparable figures for breast

**Table 4.** Rate ratios of age-adjusted cancer mortality rates for Hispanics compared with those for non-Hispanic whites\*

Cancer site	Rate ratio					
	San Antonio		San Diego		San Francisco	
	Males	Females	Males	Females	Males	Females
All sites	0.8	0.8	0.7	0.7	0.6	0.5
Esophagus	0.6	0.5	0.7	0.3	0.5	0.5
Stomach	1.9	1.6	1.8	2.4	1.5	1.7
Colon	0.6	0.8	0.5	0.6	0.5	0.6
Rectum	1.7	1.6	0.5	0.6	0.8	0.5
Liver	2.8	3.0	1.4	1.5	1.9	2.0
Gallbladder	2.0	4.4	4.0	5.3	1.6	0.1
Lung	0.6	0.4	0.6	0.4	0.4	0.3
Urinary bladder	0.6	0.5	0.6	0.9	0.5	0.3
Breast		0.7		0.5		0.5
Uterine cervix		2.9		2.6		1.2
Prostate	0.5		0.8		0.5	
Testis	0.3		0.7		0.7	

\*Source: National Hispanic Leadership Initiative on Cancer: Incidence, Mortality and Behavioral Risks Among Hispanics, 1993.



cancer showed a 50% deficit for Hispanic women in California and a 30% deficit in Texas. However, higher rates of death from cancers of the stomach, liver, and gallbladder were reported for Hispanics, and Hispanic women also were at high risk of death from cancers of the cervix and thyroid.<sup>2</sup> In Texas, Mexican-American females are twice as likely to die of cervical cancer than non-Hispanic white women (31). Rates of death from stomach cancer were 50% higher in San Francisco Hispanics and more than twice as high in Hispanic women in San Diego. For liver cancer, Texas Hispanics showed rates three times higher than those found in non-Hispanic whites. In addition, women had a particularly higher risk of gallbladder cancer than men, with rates four to five times higher in Texas and San Diego.<sup>2</sup>

## Discussion

Hispanic demographic trends will certainly hold implications for our nation's ability to reduce cancer mortality and promote general health. This population is growing faster than other major sectors, and high birth and immigration rates ensure a continuation of this growth. Although at present this population is very young, it is aging, and the elderly segment is increasing in size. Hispanics also rank low in terms of education and income among major components of the U.S. population. Additional factors include the low health status in relation to the rest of the nation, the large proportion of uninsured families, and the otherwise poor access to health care. These distinct demographic characteristics and barriers have a direct impact on the risk for cancer in Hispanics and on the development of prevention and control strategies.

Largely because of the high growth rate and the low educational and income levels, the image of an underclass erroneously influences our health policy toward Hispanics (2). In some areas of the country, this population is viewed as either a drain or a threat to society. Important demographic and health statistics, however, counter the popular notion of the Hispanic underclass model. Mortality rates for most causes of death are lower for Hispanics than for non-Hispanic whites. Overall life expectancy is higher for Hispanics. In Los Angeles, the incidence of low-birth-weight babies is lower among Hispanics, and neonatal and infant mortality rates are about half those of non-Hispanic whites (32). In addition, the high rate of men in the work force and the disproportionately low participation of women in government-subsidy programs do not fit common Hispanic stereotypes and further erode the underclass model as applied to this population. Such data clearly indicate that this model provides an inappropriate base for public policy (2).

Some evidence suggests that increased acculturation may have competing health consequences for Hispanics. It has been suggested (2) that, as this population more closely assumes the lifestyle of "mainstream" society, Hispanics will adopt health behaviors—good and bad—of non-Hispanic whites. On the positive side, this means greater likelihood of participation in cancer-screening procedures and of obtaining private health insurance. In contrast, it also may result in increased consumption of alcohol and tobacco among segments of the population, particularly among Hispanic women, who historically have

reported lower smoking and drinking rates than their non-Hispanic white counterparts.

Certainly, the need exists for precise and timely health data specific to each Hispanic population group. Indeed, if trends for this population include increased levels of acculturation, education, and socioeconomic status, it is important to understand the health implications of these changes. We also need to understand reasons for positive behaviors commonly exhibited and to formulate policies and programs that encourage and maintain these lifestyle choices. At the same time, more research is necessary to gain greater insight into Hispanic health problems and direct culturally effective education and prevention efforts. It is also vital to the success of these endeavors that we recognize the diversity that exists among the ethnic components of this population and resist the temptation to make broad policy generalizations. In addition, special efforts to understand the risk behaviors of new immigrants, particularly Central and South Americans, are needed. It may be helpful to examine cancer data sources from the Pan American Health Organization or the World Health Organization on cancers most common to the immigrants' countries of origin.

Major gaps exist in current collection, analysis, and dissemination of data related to Hispanic health. The need exists for a more supportive infrastructure vital to the development and implementation of research programs. We need to look at current data-collection instruments and procedures, to assess their effectiveness, and to develop innovative strategies better suited to Hispanics. Significant national data-collection systems should include statistically valid samples for the Hispanic population and its major components. In basic, applied, and clinical studies, ways must be found to involve more Hispanic researchers and to improve cross-cultural competence of non-Hispanic researchers. More epidemiologic studies should focus on causal factors and consequences and the mechanisms through which they function. Also, greater Hispanic representation is necessary on grant review committees, as well as in leadership and advisory positions at all levels of research development, program planning, and program implementation.

Specific to cancer issues, more funding is needed for research and control efforts in the Hispanic population. Increased epidemiologic research would enable us to better understand the disease in this population and learn why certain cancers are more prevalent in Hispanics than in non-Hispanic whites, while others are less prevalent. We also have insufficient data concerning the effectiveness of cancer treatment in Hispanics and how these treatment procedures affect quality of life. Additional insight into the influence of cultural and demographic considerations with regard to Hispanic participation in cancer control efforts and other health programs is needed. To increase awareness and invalidate misconceptions, greater effort should be directed at optimal ways to disseminate information about cancer risk factors and the importance of personal behavior in fighting this disease.

While Hispanic mortality rates are lower than those among non-Hispanic whites for major cancers, such as lung and breast cancers, epidemiologic evidence indicates that rates of death from these diseases are on the rise (30). However, these and other noncommunicable diseases prevalent among non-Hispanic



whites have not yet fully emerged in the Hispanic population. For this reason, the opportunity exists for primordial prevention or action to prevent the adoption of lifestyles and other conditions that would likely result in increased incidence of non-communicable diseases. For Hispanics, effective primordial prevention efforts would link higher education and affluence levels to the assimilation of positive health behaviors rather than negative behaviors of the dominant culture. For example, strong education and health promotion campaigns should be implemented in a culturally appropriate context that would discourage smoking and drinking but would encourage exercise, proper nutrition, and preventive care. Optimal results can be achieved by enlisting local participation in combined efforts of individuals, institutions, and community organizations.

In addition to adopting strong research, education, and prevention measures, it is absolutely essential that we find the resolve and the means to eliminate barriers that Hispanics face in obtaining health care. That one third of this population lack any form of health insurance should not be acceptable in our society. Health insurance coverage should be comprehensive, affordable, secure, open to choice, unbiased to existing conditions, and culturally responsive. The need exists for a more equitable distribution of health care providers, particularly those who are Hispanic and bilingual, in inner city and rural areas that are traditionally underserved. We need to intensify efforts to provide easily accessible, user-friendly, and nondiscriminatory health services throughout the country.

The consequences of inaction in adopting effective health care reform that addresses these issues can be measured in various ways. The consequences of not adopting a comprehensive health plan would include the continued upward spiral of medical costs for society as a whole, the burden placed on public health facilities and personnel, increased political conflict over access to quality health care, and, most importantly, the price of human suffering among those who can least afford to pay.

In conclusion, researchers must have a thorough understanding of the Hispanic population's diversity with regard to demographics, geographic distribution, acculturation levels, and barriers to health care to develop and implement cancer prevention and control research that is meaningful and that can be delivered in a culturally appropriate manner.

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# Use of Spanish Surnames to Identify Latinos: Comparison to Self-Identification

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Difficulties in identification of Latinos from secondary datasets have often been addressed by the use of a Spanish surname list. To evaluate the sensitivity and specificity of the 1980 U.S. Census Spanish surname list in correctly identifying Latino ethnicity, we conducted a cross-sectional survey of adult members of a prepaid health plan in the San Francisco Bay Area. We compared a randomly selected list of 1345 Spanish surnames and 717 non-Spanish surnames from health plan membership lists with their self-identified race and ethnicity obtained by telephone interviews. The sample was stratified according to surname group (Spanish or non-Spanish), sex, age, and county. Compared with self-identified ethnicity, a Spanish surname was 88.4% sensitive in identifying Latino men and 70.4% sensitive in identifying Latina women. The non-Spanish surname list was 94.1% sensitive and 95.0% specific in correctly identifying non-Latinos. Although the overall negative predictive value was 97.8%, the positive predictive value of a Spanish surname was only 68.3% for men and 55.7% for women. The low positive predictive value was largely due to the 316 (61%) Filipinos among the 517 persons with Spanish surnames who were not Latinos. We conclude that the use of the Spanish surname list alone to ascertain race and ethnicity in the San Francisco Bay Area both falsely identifies a large number of non-Latino persons as Latino and fails to identify a small proportion of Latinos. Although the level of sensitivity and specificity for Spanish surnames will vary with the area under study, this source of inaccuracy must be considered in studies that plan to use data based on Spanish surnames. [Monogr Natl Cancer Inst 18:11-15, 1995]

Latinos are one of the fastest growing ethnic groups in the United States, with an estimated 22 million in the 1990 U.S. Census (1). Although most Latinos are racially white, Latinos may belong to any racial group. Many Puerto Rican, Dominican, and Cuban immigrants have admixture with or are of African background; some Mexican Americans may identify themselves as or have substantial admixture with American Indians. There are even Latinos who are genetically and culturally of Asian background, especially among immigrants from the Caribbean basin and parts of South America. Because of the differentiation between race and ethnicity and the political importance of a more accurate enumeration of Latinos, the U.S. Census established the category of "Hispanics" independent of

racial background prior to the 1980 census (2). This was designed to comply with uniform standards for data collection by federal agencies (3).

Traditional methods for racial classification were based on skin color and physical characteristics. The U.S. Census asks respondents to self-categorize their race (white, black, Asian, or Native American) and then determine Hispanic ethnicity (1). There is a lack of scientific consensus on the measurement of race and ethnicity as variables in public health surveillance, and a scientific and public discussion of this issue is ongoing (4).

Methods that have been used to identify Latino ethnicity include the U.S. Census list of Spanish surnames (5), birthplace, national background of parents and grandparents (6), language use, perceived ethnicity by staff (7), and self-categorization. Whenever an individual is available for an interview, direct questioning about ethnic self-identification to ascertain ethnicity is used by health care researchers. However, there is no consensus on a gold standard definition of ethnicity, and ultimately, multiple criteria that include birthplace, family background, culture, language use, and self-identity may need to be incorporated into defining an ethnic group (4). To ascertain a specific Latino national background, origin of parents and grandparents can better define a Mexican American, for example, than simple self-categorization (6). Finally, there are situations where neither of these methods can be applied initially, such as in large databases, where ethnicity was not ascertained at the time data were collected. It is in these situations that the use of the Spanish surname list provides an inexpensive alternative to identify a Latino sample. However, the use of Spanish surname lists to identify Latinos has its own limitations (8).

We evaluated the usefulness and limitations of identifying a sample of Latinos by using the list of Spanish surnames from the 1980 U.S. Census (5). The file of Spanish surnames was matched to names in the membership list of a large prepaid health care plan located in northern California, an area of high ethnic and racial diversity.

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See "Notes" section following "References."

## Methods

Current members of the Kaiser Permanente Medical Care Program (KPMCP) in San Francisco and Alameda Counties between the ages of 35 and 74 years who had been members for at least 5 years were eligible for a study comparing Latinos and Anglos (non-Latino whites) on knowledge, attitudes and behavior about cancer in general, its early detection, and its prevention. Eligible members were identified from the KPMCP computer-stored membership files that listed name, sex, age, location of medical care, and telephone number. Maiden names were not available from the KPMCP membership files. Because race or ethnicity were not available from membership files, we used the U.S. Census list of Spanish surnames (5) to define the sampling frame, and a random sample of Spanish surnames and non-Spanish surnames was selected. The sample was stratified by surname to produce Spanish surnames at a ratio of 2:1 to non-Spanish surnames. Each sample by surname category was evenly divided by sex and by county.

Race or ethnicity was ascertained by self-identification at the time of the interview by asking the following question: "Do you consider yourself to be Hispanic, Latino or Chicano, Caucasian or white, black or African-American, Asian or Asian-American, Filipino or Pacific Islander, or Native American or American Indian?" If a respondent self-identified as white, black, Asian or Asian-American, Filipino or Pacific Islander, or American Indian, they were asked if they considered themselves Hispanic, Latino, or Chicano. The interview study on cancer was conducted only with Latino and Anglo respondents who agreed to participate.

The KPMCP in northern California has more than 2.4 million members and serves about 30% of the population in the San Francisco Bay Area. Members, who are mostly employed, represent the full spectrum of age, socioeconomic background, and racial/ethnic diversity. Comparison with the U.S. Census population in the Bay Area indicated that the membership is demographically similar, except that it underrepresents the extremes of socioeconomic status (9). Regional patient surveys have shown that approximately 10% of the membership self-identify as Latino.

Self-identified race or ethnicity was used as the standard to calculate sensitivity, specificity, and the predictive values of positive and negative designations as Latino on the basis of a Spanish surname. Sensitivity was defined as the proportion of self-identified Latinos with Spanish surnames; specificity was defined as the proportion of self-identified non-Latinos of any race with a non-Spanish surname; positive predictive value was defined as the proportion of persons with Spanish surnames who self-identified as Latino; and negative predictive value was defined as the proportion of non-Latinos with non-Spanish surnames. The study sample was weighted according to how the total KPMCP population was stratified in selecting the sample. The actual number interviewed in each category of surname was divided by the probability of being selected from the total membership population. Chi-squares were calculated where appropriate.

## Results

The sample was drawn from a denominator of 193 550 surnames of eligible KPMCP members. The Spanish-surnamed

sample was selected from a list of 22 835 persons and the non-Spanish-surnamed sample was selected from a list of 170 715 persons.

Of the 1867 Spanish-surnamed persons selected, race or ethnicity was ascertained in 1345 (72%). Among the remaining names, 91 (4.9%) persons refused interviews before responding to the screening question, 29 (1.6%) were not contacted because of vacation or illness, 57 (3.1%) were not contacted after 10 attempts, seven (0.4%) were business numbers, and 338 (18.1%) were nonworking or out-of-date telephone numbers. Of the 1006 non-Spanish-surnamed KPMCP members identified, race or ethnicity was ascertained in 717 (71.3%), 55 (5.5%) persons refused interviews, 26 (2.6%) persons were not reached because of vacations or illness, 68 (6.8%) were not contacted after 10 attempts, nine (0.9%) were business numbers, and 131 (13%) were nonworking or out-of-date telephone numbers. The remainder of this report is restricted to the 2062 persons with ascertained race or ethnicity.

Of the 1345 Spanish-surnamed persons with ascertained race or ethnicity, 53.4% were women, the mean age was 50.9 years, and 50% lived in San Francisco. Of the 717 persons with non-Spanish surnames and ascertained race or ethnicity, 52.2% were women, the mean age was 52 years, and 56.6% lived in San Francisco.

Initial categorization by surname was compared with self-identified race or ethnicity for men and women (Table 1). Most Latinos identified had a Spanish surname. Among Spanish-surnamed persons, a greater proportion of men compared with women were Latinos (68.3% versus 55.7%;  $\chi^2 = 22$ ;  $df = 1$ ;  $P < .001$ ). About 12% of Spanish-surnamed persons self-identified as non-Latino whites, and white women were more likely than white men to have a Spanish surname (16.4% versus 6.5%;  $\chi^2 = 33$ ;  $df = 1$ ;  $P < .001$ ).

Nearly one quarter of persons with Spanish surnames were Filipinos equally divided by sex. Of the 517 persons with Spanish surnames, but who identified themselves from race or ethnic groups other than Latino, 316 (61.1%) were Filipinos, 159 (30.7%) were white, 27 (5.2%) were Asian, eight (1.5%) were African-American, and seven (1.4%) were American Indian. By comparison, only 16 of 717 (2.2%) persons with non-Spanish surnames were Latinos, of which 12 of 16 were women. The proportion of African-Americans and Asians in the non-

**Table 1.** Comparison of self-identified ethnicity with categorization by surname list in KPMCP members, 1990

	Spanish surnames				Non-Spanish surnames			
	Men		Women		Men		Women	
	No.	%	No.	%	No.	%	No.	%
Race/ethnicity determined	627	100	718	100	343	100	374	100
Race/ethnicity								
Latino/Hispanic	428	68.3	400	55.7	4	1.2	12	3.2
White/Anglo	41	6.5	118	16.4	179	52.2	194	51.9
African-American	4	0.6	4	0.6	61	17.8	75	20.1
Filipino	139	22.2	177	24.7	17	5.0	22	5.9
Other Asian	13	2.1	14	1.9	79	23.0	65	17.4
American-Indian	2	0.3	5	0.7	3	0.9	6	1.6



Spanish-surnamed list was similar to that of the general KPMCP population.

The sample of 1345 Spanish surnames had a probability of .0589 of being selected, and the sample of 717 non-Spanish surnames had a probability of .0042 of being selected. Dividing the actual number of Spanish-surnamed, self-identified Latino and non-Latino respondents by the probability of .0589 resulted in the weighted samples shown in Table 2 for men and women. Similarly, the weighted sample of non-Spanish-surnamed Latinos and non-Latinos was calculated by dividing the actual number of respondents by .0042. The weighted sample was then used to calculate the sensitivity and specificity, by sex, of Spanish surnames to identify Latinos compared with self-report as the reference criterion (Table 3).

The overall sensitivity of Spanish surnames for identifying Latinos was 78.7% (14 058 of 17 868), but 38.4% (8778 of 22 836) of persons with Spanish surnames were not Latinos. Spanish surnames were more sensitive in identifying Latino men (88.4%) than women (70.4%). The specificity of Spanish surnames in correctly categorizing non-Latinos was 95.0% (166 905 of 175 683), and similar specificities were noted by sex (96.0% for men and 94.1% for women). The positive predictive value of Spanish surnames in identifying Latinos was 68.3% (7266 of 10 645) for men and only 55.7% (6791 of 12 190) for women. Since only 2.2% of persons with non-Spanish surnames were Latinos, the negative predictive value of Spanish surname categorization was 98.8% and 96.8% for men and women, respectively.

## Discussion

Our report compared the validity of Spanish surnames with the gold standard of self-identification in the multiethnic environment of the San Francisco Bay Area with a large Latino and Asian- and African-American population. Spanish surnames were moderately sensitive in identifying Latinos, although surprisingly few Latinos had non-Spanish surnames in this study. This may reflect the Mexican and Central American national origin of 80% of Latinos interviewed, with only 20% coming from the rest of Latin America, including countries that are more likely to have had non-Spanish European immigrants (e.g., Argentina).

**Table 2.** Comparison of surname category with self-identified ethnicity in KPMCP members, 1990

	Self-identified ethnicity*		Totals
	Latino	Non-Latino	
Men			
Spanish surname	7266 (428)	3379 (199)	10 645 (627)
Non-Spanish surname	952 (4)	80 714 (339)	81 666 (343)
Totals	8218 (432)	84 093 (538)	92 311 (970)
Women			
Spanish surname	6791 (400)	5399 (318)	12 190 (718)
Non-Spanish surname	2857 (12)	86 190 (362)	89 047 (374)
Totals	9648 (412)	91 589 (380)	101 237 (1092)

\*Numbers in parentheses = actual numbers of respondents with ascertained ethnicity.

Although the specificity of non-Spanish surnames in identifying non-Latinos was excellent, the positive predictive value of Spanish surnames in this population was 68% for men and only 56% for women (total, 61.6%). This was due not only to non-Latino whites with Spanish surnames (especially women) but also to the large Filipino population. The 1990 U.S. Census estimated that 6% of the population of San Francisco and 4% of the population of Alameda County were Filipino (1). Many Filipinos have Spanish surnames because of the nearly 400 years of Spanish colonization, but despite this historical fact, the vast majority of Filipinos do not self-identify as Latino or Hispanic. The value of using Spanish surnames to define a sample of Latinos is thus limited in the San Francisco Bay Area.

To our knowledge, there are only three previous studies that have compared use of Spanish surnames with a reference criterion in a large sample of U.S. Latinos (Table 3) (6,10,11). Howard et al. (10) compared self-identity with the 1980 Census Spanish surname list and a computer program designed to identify surnames of selected ethnicities in a sample of Albuquerque residents. The sensitivity and specificity of the census list were similar to our study among men, and better sensitivity and slightly lower specificity were found for women (Table 3) (10). With the use of both the census list and the computer program, sensitivity was increased to 90% for men and 84% for women,

**Table 3.** Sensitivity, specificity, and predictive value of Spanish surnames category compared with self-identified Latino ethnicity

	Albuquerque, 1979 (10)		San Antonio,* 1979-1982 (6)		Northern California,† 1979-1980 and 1989-1990 (11)		KPMCP, 1990	
	% men	% women	% men	% women	% men	% women	% men	% women
Sensitivity	85	79	96	92	89	80	88	70
Specificity	95	90	80	66	95		96	94
Positive predictive value	NA‡	NA	86	77	83	74	68	56
Negative predictive value	NA	NA	95	87	99		99	97

\*San Antonio data are shown by age groups 24-44 and 45-64 years for individual surname characteristics.

†Northern California data were calculated from the tables presented in the paper; number of non-Hispanics with non-Spanish surnames was not included by sex and thus specificity and negative predictive value cannot be calculated separately by sex.

‡NA = not available.



and the specificity was increased to 97% for men and 91% for women (10).

With the goal of identifying persons of a single national origin, Hazuda et al. (6), in the San Antonio Heart Study, reported on the usefulness of individual surnames compared with the reference criterion of having three of four Mexican grandparents in identifying Mexican Americans. Sensitivity and specificity varied slightly by age groups and by sex and are shown in Table 3. The overall sensitivity of individual surnames was 95%, and the specificity was 75% (6). Our results from the KPMCP study showed that the census list had a lower sensitivity and a higher specificity than in the Texas study. This is likely to reflect not only the more heterogeneous population residing in California, but also specifically the large Filipino population.

Winkleby and Rockhill (11) compared self-reported Hispanic ethnicity and categorization by Spanish surname in 4918 individuals (13.7% Hispanic) surveyed during evaluations of the Northern California Five City Project. Their analyses showed that the Spanish surname list had an overall sensitivity of 84.1% and a specificity of 77.9% when compared with self-identification. A higher concordance between the two methods was found for men and those who were primarily Spanish speaking, but only 35% (39 of 111) of married English-speaking women with Spanish surnames self-identified as Hispanics (11). Comparison of our data with the Five City Project analysis shows that the list of Spanish surnames had similar sensitivity for men, higher sensitivity for women, and similar overall specificity in identifying Latinos. The increased likelihood of misclassification when using Spanish surname lists in areas such as northern California with a substantial Filipino population is acknowledged (11).

Comparison of the performance of the Spanish surname list across the four studies confirms the limitations of solely using this method to identify Latinos. Although in the Texas and California studies the negative predictive value exceeded 95% for most categories, the average positive predictive value was only about 74% (Table 3) (6,11). Thus, although relatively few non-Latinos would be included in a sample identified by Spanish surnames, up to one quarter would be excluded from the sample denominator by sole use of this method. It is noteworthy that no studies have been conducted to compare Spanish surname with self-identity in Latino populations, other than in the southwestern states.

The absence of specific ethnic identity in a given database may hinder research with populations such as Latinos who may be categorized in other racial groups. For example, national hospital discharge databases do include Hispanic ethnicity, but the information on Hispanic origin is often missing. Similar situations may exist in selected states with data from cancer registries, death certificates, and birth certificates (12), although since 1989, standard registration forms included a Hispanic identifier for the first time. The Spanish surname list has been applied as the sole method to identify Latinos in some research reports (13,14). The potential flaws in this method include lack of sensitivity in identifying Latinos with non-Spanish surnames, lack of specificity because persons of Italian and Portuguese (or in our case, Filipino) heritage may be included in lists of Spanish surnames, and the added misclassification created when women

assume a married non-Spanish surname or a married Spanish surname (8).

Imprecise ascertainment of ethnicity may affect cancer incidence and mortality rates. Undercount of ethnic minorities by the U.S. Census may decrease the denominator and falsely increase population disease rates. Misclassification of patients' ethnicity with cancer may also affect ethnic-specific cancer rates. Since there is no systematic method of ascertaining race and ethnicity at the hospitals that are reporting cancer cases, misclassification may alter rates in either direction. One study (15) reported that obtaining a woman's maiden name and applying this to a dataset of surnames probably decreases misclassification of women by Latino ethnicity. An unpublished study in northern California compared different methods to classify Hispanic cancer patients, including self-report, surname list, and the New Mexico computer program, and found that the sensitivity was about 60% for any single method. The relative bias of single methods was toward a decrease in Latino cancer rates, and applying a combination of methods may reduce the bias in incidence rates (16).

Use of Spanish surname lists in identifying Latinos for research studies offers some possible advantages. Spanish surname lists facilitate use of databases without ethnic identifiers, allow selection of names from telephone directories to conduct a population-based survey, and overall are easier to use than interviewing potential subjects to classify ethnicity. Because of the expense of census tract-based sampling, the random-digit dialing method is usually applied only in areas with at least 10% Latinos to maximize the number of completed interviews. However, use of Spanish surname lists and a telephone directory may allow researchers to include subjects living throughout an urban area. This may result in a study population with a wider spectrum of socioeconomic status and specifically include more middle-class Latinos. Although possible advantages may outweigh the established disadvantages of solely depending on Spanish surname lists to identify Latinos, these limitations need to be recognized by researchers.

This study has several limitations. Self-reported race or ethnicity may also result in errors in classification when the respondent does not fully comprehend the racial or ethnic categories (12). Additional questions on racial or ethnic background of parents and grandparents can help verify the self-reported category, and the reliability of responses to a single item also needs to be considered. Misclassification errors are magnified when comparing different subgroups within a broad racial or ethnic category and thus are likely to have been limited in our data that focus on identification of all Latinos. Ethnicity was ascertained in about 72% of the randomly selected surnames, and those persons unavailable for interview may have influenced the results. Finally, our analysis was based on a Latino sample from the San Francisco Bay Area, and regional differences of Latino national background may limit the generalizability of these results.

We conclude that the use of Spanish surname lists alone to identify Latino populations has important limitations in a multi-ethnic environment. Research results based on a Latino sample selected only by this method should be interpreted with caution. The limitations of using a Spanish surname list to identify a



sample need to be considered prior to addressing a research question relevant to Latino health care.

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# Epidemiology of Cancer Among Hispanics in the United States

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**Background:** There are very limited data on cancer among U.S. Hispanics. The data that are available seldom appear outside individual registry reports. Without coalescing and assessing such information, the epidemiology of cancer among Hispanics cannot be understood. **Purpose:** This article presents an overall view of the epidemiology of cancer among Hispanic populations in the United States. **Methods:** Major types of cancer were reviewed from geographic areas with 1) large Hispanic/Latino populations and 2) population-based cancer registry data for Hispanics. This review includes registries that cover 68% of the U.S. Hispanic population. Age-standardized rates, standardized rate ratios, and ranks of the top cancers are presented for Hispanics and non-Hispanics by sex. **Results:** Hispanic men had consistently lower rates of cancers of the lung, prostate, colon, rectum, and oral cavity as well as of melanoma and non-Hodgkin's lymphoma than non-Hispanic men. Among Hispanic men, higher rates were observed for cancers of the stomach, liver, and gallbladder. Compared with the rates in non-Hispanic women, Hispanic women had consistently lower rates of cancers of the breast, colon, rectum, endometrium, lung, ovary, and oral cavity, non-Hodgkin's lymphoma, and melanoma and higher rates of cancers of the uterine cervix, stomach, liver, and gallbladder. Perhaps more importantly, however, was that, within U.S. Hispanic populations, the top five sites of cancer for women were breast, colon, lung, cervix, and uterine corpus. For men, the top sites were usually prostate, lung, colon, stomach, and rectum. Furthermore, some geographic areas showed differences in the order of importance within these five sites, while in other areas, the top five cancers for Hispanic men included kidney and bladder cancers, liver cancer, and non-Hodgkin's lymphomas. For women, other leading cancers mentioned were ovarian cancer, non-Hodgkin's lymphoma, and gallbladder cancer. **Conclusions:** Hispanics had consistently lower rates of breast, lung, prostate, and colon cancers than non-Hispanics. In some geographic regions, however, differences in cancer incidence rates with respect to specific sites existed between the heterogeneous Hispanic populations. Furthermore, the rankings demonstrated that, even if Hispanics have lower rates of the most common cancers than non-Hispanics, such sites are still the most important cancers among Hispanic populations. **Implications:** Cancer is a major problem among U.S. Hispanic populations. The information given in this article can be used to develop etiologic studies and cancer control in-

terventions. Data limitations and recommendations for improving data quality are presented. [Monogr Natl Cancer Inst 18:17-28, 1995]

This year the number of new cases of cancer diagnosed among Hispanics in the United States is unknown. The highest rates of cancer among Hispanics are also unknown, as is the epidemiology in general. Malignant neoplasms are the second leading cause of death among U.S. Hispanics, yet there is strikingly little information available about the incidence of cancer among Hispanics in the U.S. population. Furthermore, when existing information has been published, it has usually been limited to state or municipal registry reports. In the next few years, the expansion of the Surveillance, Epidemiology, and End Results (SEER) Program<sup>1</sup> of the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention's National Program of Cancer Registries<sup>2</sup> will undoubtedly be able to provide more complete information about the incidence of cancer among Hispanics. Until such time, this article presents a compilation of information on the incidence and epidemiology of cancer among U.S. Hispanics. Data were obtained 1) from areas that had population-based cancer registries, that collected relevant data in a timely and systematic manner, and that had sizable Hispanic populations and 2) from published reports. We include information about cancer from regional registries covering 68% of the U.S. Hispanic population.

## Methods

The information in this article was obtained from both cancer registry records in the United States (1-5) and published research articles (6-9). The geographic areas included here are those that have sizable Hispanic populations and available age-standardized incidence rates by sex that identify, in some form, Hispanics. The geographic areas included were Los Angeles County, Calif.; the San Diego area in California; the San Francisco Bay Area in California; the entire state of California; the El Paso and Lubbock areas in Texas; the Denver area in Colorado; New York City, N.Y.; the Commonwealth of Puerto Rico; Dade County, Fla.; the Chicago area in Illinois; and the states of New Mexico and Illinois.

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See "Notes" section following "References."



We have chosen to do our analyses using incidence data from population-based registries for two reasons. First, a population-based registry is not as likely as an individual study to be limited by selection criteria or selection bias; as such, it will present incidence rates that more truly reflect the occurrence of cancer in the geographic area. Second, incidence data usually have comparable definitions for disease and are relatively consistent in coding. In addition, other measures, such as prevalence or mortality, are influenced by a variety of factors, such as access to diagnostic and/or treatment facilities.

This analysis consists of several parts. For each geographic area, the five most common sites of cancer incidence were ranked first by sex and ethnicity. These rankings were based on age-standardized incidence rates. All rates were standardized by the direct method, using the U.S. standard 1970 million population. Next, comparisons among Hispanics were made between sexes. Finally, standardized rate ratios (SRRs) of cancer of specific sites were calculated comparing Hispanics with non-Hispanics. SRRs were calculated for 14 cancer sites or types (breast, cervix, colon, endometrium, gallbladder, oral cavity/pharynx, ovary, prostate, liver, lung, melanoma, non-Hodgkin's lymphoma, rectum, or stomach) and all sites combined. These sites were selected on the basis of high incidence or the importance of the site for Hispanics. SRRs greater than 1.0 indicate an increased rate of cancer among Hispanics, compared with non-Hispanics; SRRs less than 1.0 imply lower rates for Hispanics.

From each registry, the most currently available data were used. Most cases were diagnosed from 1988 through 1991, but there were variations in the years available. Each report that was used was based on at least 3 years of data accrual.

The term "Hispanic" is used throughout the article to describe Mexican-Americans, Puerto Ricans, Cuban-Americans, Central Americans, South

Americans, persons from other Spanish-speaking Caribbean countries, and persons from Spain, currently living in the United States. The term "non-Hispanic" is defined in this article as any individual not of Hispanic origin. In most instances, "non-Hispanic," "white non-Hispanic," and "Anglo" were used interchangeably by the registries. This is true for the El Paso and Lubbock areas, San Diego and San Francisco Bay areas, as well as Los Angeles County, the Denver area, the state of Mexico, and New York City.

For both the Chicago area and the state of Illinois, "non-Hispanic" referred to the total non-Hispanic population, irrespective of race. Because the population of Puerto Rico is nearly completely Hispanic, their rates were compared with those of the white population of the United States. Only Dade County, Fla., had incidence rates stratified simultaneously by race and ethnicity. Because there was effect modification by race in south Florida, data for white Hispanics and black Hispanics are presented separately.

Differences in definitions of Hispanics and non-Hispanics between registries serve as a caution with regard to interpretation of data, but their limitations do not prevent assessment of site-specific SRRs. By calculating these SRRs for several geographic regions, one can compare incidence from one area to another to identify geographic differences or consistencies, which, in turn, can suggest implications for specific Hispanic populations.

## Results

The top five sites are presented in Table 1 for men and in Table 2 for women.

**Table 1.** Leading sites or type of cancer and age-standardized rates among Hispanic men and non-Hispanic men

<i>Hispanic men*</i>													
Puerto Rico, 1988-1990	Lubbock area, 1976-1985	El Paso area, 1976-1984	Chicago area, 1986-1990	Illinois, 1986-1990	Dade County whites, 1981-1989	Dade County blacks, 1981-1989	New York City, 1982-1985	Denver area, 1988-1990	San Diego area, 1988-1991	Los Angeles County, 1988-1991	San Francisco Bay Area, 1988-1991	California, 1988-1991	New Mexico, 1988-1992
Prostate (57.0)	Lung (43.0)	Prostate (71.4)	Prostate (61.6)	Prostate (70.0)	Lung (59.5)	Prostate (52.7)	Prostate (59.8)	Prostate (78.8)	Prostate (96.5)	Prostate (72.7)	Prostate (88.8)	Prostate (81.9)	Prostate (100.8)
Lung (20.9)	Prostate (32.9)	Lung (45.8)	Lung (46.5)	Lung (56.6)	Prostate (56.5)	Lung (50.5)	Lung (51.5)	Lung (50.9)	Lung (61.0)	Lung (41.8)	Lung (49.7)	Lung (45.4)	Lung (34.5)
Oral (18.1)	Colon (17.6)	Stomach (16.9)	Colon (26.2)	Colon (31.5)	Colon (30.7)	Colon (26.2)	Colon (24.8)	Colon (24.3)	Colon (19.9)	Colon (23.8)	Colon (29.7)	Colon (23.9)	Colon (24.9)
Colon (15.8)	Pancreas (13.3)	Colon (16.3)	Rectum (16.6)	Bladder (20.2)	Bladder (27.9)	Oral cavity (16.8)	Stomach (18.7)	Rectum (21.5)	Stomach (19.0)	Stomach (15.0)	NHL (21.8)	Stomach (14.8)	Stomach (16.6)
Stomach (15.7)	Stomach (12.0)	Kidney (13.8)	Bladder (16.3)	Rectum (18.0)	Oral cavity (14.3)	Stomach (15.9)	Rectum (13.0)	Oral cavity (13.4)	NHL (14.5)	NHL (12.5)	Rectum (17.2)	NHL (13.3)	Bladder (13.8)
All sites, No. of cases = 12 271	All sites, No. of cases = 369	All sites, No. of cases = 1773	All sites, No. of cases = n/a	All sites, No. of cases = n/a	All sites, No. of cases = 10 417	All sites, No. of cases = 172	All sites, No. of cases = 1087	All sites, No. of cases = 554	All sites, No. of cases = 1839	All sites, No. of cases = 8248	All sites, No. of cases = 2233	All sites, No. of cases = 21 052	All sites, No. of cases = 3214
<i>Non-Hispanic men*</i>													
U.S. whites, 1988-1990	Lubbock area, 1976-1985	El Paso area, 1976-1984	Chicago area, 1986-1990	Illinois, 1986-1990	Dade County whites, 1981-1989	Dade County blacks, 1981-1989	New York City, 1982-1985	Denver area, 1988-1990	San Diego area, 1988-1991	Los Angeles County, 1988-1991	San Francisco Bay Area, 1988-1991	California, 1988-1991	New Mexico, 1988-1992
Prostate (107.3)	Lung (72.0)	Lung (76.5)	Lung (86.3)	Prostate (83.5)	Lung (72.8)	Prostate (97.6)	Lung (73.2)	Prostate (138.8)	Prostate (136.0)	Prostate (119.5)	Prostate (120.2)	Prostate (120.7)	Prostate (151.3)
Lung (81.2)	Prostate (60.4)	Prostate (74.9)	Prostate (85.7)	Lung (82.1)	Prostate (56.8)	Prostate (86.8)	Prostate (55.2)	Lung (67.9)	Lung (82.5)	Lung (79.5)	Lung (77.4)	Lung (83.2)	Lung (66.7)
Colon (41.0)	Colon (23.9)	Colon (30.3)	Colon (45.4)	Colon (43.8)	Colon (43.8)	Colon (26.0)	Colon (46.7)	Colon (35.8)	Colon (38.6)	Colon (40.3)	Colon (40.1)	Colon (38.4)	Colon (31.1)
Bladder (32.4)	Bladder (18.8)	Bladder (26.8)	Bladder (27.6)	Bladder (28.2)	Bladder (30.3)	Oral cavity (21.9)	Rectum (20.2)	NHL (16.2)	NHL (18.1)	Bladder (24.3)	NHL (27.5)	Bladder (24.5)	Bladder (30.2)
Rectum (18.8)	Oral cavity (16.5)	Oral cavity (18.5)	Oral cavity (17.8)	Rectum (19.6)	Rectum (16.1)	Other (19.7)	Stomach (13.4)	Rectum (15.1)	Melanoma (17.2)	Rectum (16.9)	Bladder (26.8)	NHL (19.3)	Melanoma (19.5)
All sites, No. of cases = 427 484	All sites, No. of cases = 4141	All sites, No. of cases = 2785	All sites, No. of cases = n/a	All sites, No. of cases = n/a	All sites, No. of cases = 17 013	All sites, No. of cases = 2906	All sites, No. of cases = 10 063	All sites, No. of cases = 8301	All sites, No. of cases = 17 605	All sites, No. of cases = 42 102	All sites, No. of cases = 25 259	All sites, No. of cases = 178 797	All sites, No. of cases = 10 229

\*Entries in columns = leading cancer sites or type (age-standardized rates). NHL = non-Hodgkin's lymphoma; n/a = data not available.



**Table 2.** Leading sites or type of cancer and age-standardized rates among Hispanic women and non-Hispanic women

<i>Hispanic women*</i>													
Puerto Rico, 1988-1990	Lubbock area, 1976-1985	El Paso area, 1976-1984	Chicago area, 1986-1990	Illinois, 1986-1990	Dade County whites, 1981-1989	Dade County blacks, 1981-1989	New York City, 1982-1985	Denver area, 1988-1990	San Diego area, 1988-1991	Los Angeles County, 1988-1991	San Francisco Bay Area, 1988-1991	California, 1988-1991	New Mexico, 1988-1992
Breast (59.8)	Breast (33.5)	Breast (58.8)	Breast (90.2)	Breast (107.4)	Breast (72.7)	Breast (59.5)	Breast (53.2)	Breast (84.6)	Breast (70.3)	Breast (64.3)	Breast (87.4)	Breast (69.1)	Breast (71.9)
Colon (17.9)	Uterine cervix (24.8)	Uterine cervix (23.5)	Uterine cervix (44.8)	Uterine cervix (46.9)	Colon (26.5)	Colon (16.7)	Colon (20.4)	Colon (21.1)	Lung (25.7)	Uterine cervix (18.3)	Lung (29.2)	Lung (21.2)	Colon (19.0)
Uterine cervix (12.6)	Gallbladder (12.9)	Lung (16.0)	Lung (25.7)	Colon (31.8)	Uterine corpus (17.1)	Uterine corpus (13.4)	Uterine cervix (19.4)	Lung (19.2)	Uterine cervix (17.6)	Lung (18.2)	Colon (22.2)	Colon (17.1)	Lung (17.0)
Uterine corpus (11.2)	Lung (11.8)	Colon (15.4)	Colon (24.8)	Lung (29.7)	Lung (13.0)	Uterine cervix (12.0)	Lung (14.1)	Uterine corpus (13.3)	Colon (16.1)	Colon (15.7)	Uterine corpus (17.7)	Uterine cervix (16.9)	Uterine corpus (10.6)
Lung (9.6)	Uterine corpus (11.7)	Uterine corpus (12.8)	Uterine corpus (18.6)	Uterine corpus (21.0)	Ovary (12.1)	Lung (9.6)	Stomach (8.4)	Uterine cervix (9.7)	Ovary (11.2)	Uterine corpus (13.0)	NHL (15.2)	Uterine corpus (13.5)	Uterine cervix (10.1)
All sites, No. of cases = 9948	All sites, No. of cases = 395	All sites, No. of cases = 2132	All sites, No. of cases = n/a	All sites, No. of cases = n/a	All sites, No. of cases = 10 639	All sites, No. of cases = 176	All sites, No. of cases = 1207.75	All sites, No. of cases = 600	All sites, No. of cases = 1819	All sites, No. of cases = 9250	All sites, No. of cases = 2261	All sites, No. of cases = 22 305	All sites, No. of cases = 2902
<i>Non-Hispanic women*</i>													
U.S. whites, 1988-1990	Lubbock area, 1976-1985	El Paso area, 1976-1984	Chicago area, 1986-1990	Illinois, 1986-1990	Dade County whites, 1981-1989	Dade County blacks, 1981-1989	New York City, 1982-1985	Denver area, 1988-1990	San Diego area, 1988-1991	Los Angeles County, 1988-1991	San Francisco Bay Area, 1988-1991	California, 1988-1991	New Mexico, 1980-1992
Breast (112.1)	Breast (68.2)	Breast (80.6)	Breast (117.3)	Breast (111.7)	Breast (100.9)	Breast (70.7)	Breast (93.8)	Breast (116.6)	Breast (118.8)	Breast (124.1)	Breast (129.1)	Breast (119.0)	Breast (103.8)
Lung (40.2)	Lung (21.5)	Lung (29.3)	Uterine cervix (41.7)	Uterine cervix (40.6)	Lung (43.9)	Lung (26.1)	Colon (33.9)	Lung (34.0)	Lung (50.1)	Lung (49.0)	Lung (51.4)	Lung (50.2)	Lung (34.9)
Colon (30.2)	Colon (21.3)	Colon (25.5)	Lung (38.6)	Lung (35.4)	Colon (32.7)	Colon (26.0)	Lung (31.8)	Colon (29.8)	Colon (27.9)	Colon (29.4)	Colon (30.2)	Colon (28.6)	Colon (23.8)
Uterine corpus (21.9)	Uterine corpus (19.1)	Uterine corpus (16.8)	Colon (32.9)	Colon (33.0)	Uterine corpus (18.8)	Uterine cervix (19.4)	Uterine corpus (16.7)	Uterine corpus (21.6)	Uterine corpus (21.5)	Uterine corpus (24.7)	Uterine corpus (23.7)	Uterine corpus (22.7)	Uterine corpus (18.7)
Ovary (15.0)	Ovary (10.7)	Ovary (14.8)	Uterine corpus (20.1)	Uterine corpus (20.6)	Ovary (15.4)	Uterine corpus (15.0)	Ovary (15.6)	Ovary (13.0)	Ovary (16.8)	Ovary (17.5)	Ovary (17.3)	Ovary (16.3)	Ovary (13.6)
All sites, No. of cases = 420 775	All sites, No. of cases = 3849	All sites, No. of cases = 2688	All sites, No. of cases = n/a	All sites, No. of cases = n/a	All sites, No. of cases = 19 626	All sites, No. of cases = 3351	All sites, No. of cases = 11 030.75	All sites, No. of cases = 8567	All sites, No. of cases = 15 768	All sites, No. of cases = 41 828	All sites, No. of cases = 23 924	All sites, No. of cases = 171 488	All sites, No. of cases = 8411

\*Entries in columns = leading cancer sites or type (age-standardized rates). NHL = non-Hodgkin's lymphoma; n/a = data not available.

## Top Sites Among Men

With respect to the rank of the major sites, there was substantial intra-area consistency in rankings among Hispanic and non-Hispanic men. Almost every area had the same five sites mentioned: prostate, lung, colon, stomach, and rectum. However, only the state of Illinois had the same five sites in the same order among Hispanic and non-Hispanic men. There were a few additional cancer sites among the top five most common cancers, with the appearance of urinary bladder cancer among both Hispanic and non-Hispanic males in the Chicago area, Dade County (white), Illinois, and New Mexico; pancreatic cancer among the Hispanic males in the Lubbock area; kidney cancer among the Hispanic males in the El Paso area; and oral cancer in Puerto Rico, Dade County white and black Hispanic males, Denver area Hispanic males, and the non-Hispanic males in both the Lubbock and El Paso areas. Non-Hodgkin's lymphoma was

among the top five sites of cancer in all geographic areas of California among the Hispanic males and in all geographic areas of California with the exception of the Los Angeles area among non-Hispanic males.

For all areas, the top two cancers among Hispanic and non-Hispanic men were lung and prostate cancers. Among Hispanic men, the prostate was most commonly the highest ranked site of cancer. Only in Dade County white Hispanics and in the Lubbock area was lung cancer ranked higher than prostate cancer. Among non-Hispanic men, the prostate was also ranked most often as the top site. For lung cancer, no group of Hispanic men had a higher incidence rate than any group of non-Hispanics. White non-Hispanics in New Mexico had the highest incidence of prostate cancer of any group (Hispanic or non-Hispanic) included in these analyses. Among Hispanics, the highest rate of prostate cancer was also in New Mexico, and while their in-



cidence of prostate cancer was two thirds that in their non-Hispanic counterparts, their incidence rates were higher than those in non-Hispanic men in Illinois and Dade County blacks, who had prostate cancer ranked first.

Among Hispanic men, colon cancer was ranked the third most common cancer in every geographic region, with the exception of Puerto Rico and the El Paso area. Similarly, among non-Hispanic men, cancer of the colon ranked as the third most common site in all geographic areas. While the incidence rates of colon cancer were higher among non-Hispanics than among Hispanics in general, the higher end of the range of colon cancer incidence rates among Hispanic men was equal to or greater than the lower end of the range of incidence rates among non-Hispanic men.

For Dade County black Hispanic men, the order was the same for the top four sites of cancer: prostate, lung, colon, and oral cavity.

Melanoma appeared in the list of five most common cancers only among non-Hispanics. In contrast, with the exception of the city of New York, the stomach was never among the top five sites of cancer for non-Hispanics, but it was ranked among the top five cancer sites among Hispanic men in nine geographic regions. Thus, relatively speaking, stomach cancers are still far more important cancers in Hispanics than in non-Hispanics. Bladder cancer appeared in all but four regions as the fourth or fifth most common cancer among non-Hispanic men. Among Hispanic men, it appeared as the fourth or fifth most common cancer in only four geographic regions. Yet, while the incidence rates were somewhat lower among Hispanics than non-Hispanics, the rates overlapped between the two groups.

Non-Hodgkin's lymphomas were among the top five ranked cancers among Hispanic men in all of the California regions included in these analyses, as well as in the entire state of California. With the exception of Los Angeles County, the same held true for non-Hispanic men.

Neither the liver nor the gallbladder was among the top five cancer sites for either Hispanic or non-Hispanic men.

### Top Sites Among Women

Among Hispanic women, the top site rankings were identical to one another in the El Paso area, the Chicago area, and Los Angeles County. In the Chicago area, the top five sites among Hispanic women were the same as those among non-Hispanic women. Thus, even in the rankings of age-standardized incidence rates, there were important differences between virtually all regions included in this article.

The breast was the single most common site of cancer among both Hispanic and non-Hispanic women, across all geographic regions included. However, there was tremendous variation in the incidence rates that underlie the rankings. The incidence rate of breast cancer among Hispanic women was highest in Illinois, where the incidence was 107.4 cases per 100 000 person-years ( $c/10^5$  py). The lowest rate among Hispanic women was in the Lubbock area, where the incidence rate was 33.5  $c/10^5$  py. Among non-Hispanic women, there was also a variation in incidence rates, and although no area-specific Hispanic women's breast cancer rates exceeded those of their non-Hispanic counterparts, the incidence rates in some Hispanic populations

did exceed those in some non-Hispanic women. For example, the incidence rates of breast cancer among non-Hispanics in the Lubbock area, the El Paso area, Dade County, and New Mexico were actually lower than those among Hispanic women in Illinois.

The second most common cancer sites among Hispanic women in all regions were either the uterine cervix, colon, or lung. In many areas (Dade County, New York City, the Denver, San Diego, and San Francisco Bay areas, and Puerto Rico), colon or lung cancers were more common than cervical cancer.

The ranks of cervical cancer were usually higher among Hispanic women than among non-Hispanic women. In Dade County, the incidence rate for black Hispanic women was lower than that for black non-Hispanic women. In the Lubbock and El Paso areas, as well as in Los Angeles County, the second most common site of cancer was the uterine cervix. In these areas, the Hispanic population is predominantly of Mexican or Mexican-American origin. In both the Chicago area and in data from the entire state of Illinois, the second most common site of cancer among Hispanic women was also the uterine cervix. The Hispanic populations in these geographic regions are largely persons of Puerto Rican origin and Mexican-Americans. However, in New York City, whose Hispanic population is primarily Puerto Rican, and in Puerto Rico, the second most common site of cancer among Hispanic women was the colon.

In the Chicago area and the state of Illinois, the breast and the uterine cervix were ranked as the top two cancer sites among both Hispanics and non-Hispanics. In addition, the incidence rates of cervical cancer among non-Hispanic women in both areas were higher than those among Hispanic women in all regions.

Cancer of the uterine corpus (used interchangeably in this article with endometrial cancer) appeared within the top five cancers in many geographic regions. There was consistency in the range of incidence rates among Hispanic and non-Hispanic women in Dade County (blacks and whites), the state of Illinois, and the Chicago area. The ovary appeared in the top five sites of cancer among Hispanics in two areas, whereas among non-Hispanic women, it was among the top five sites in most geographic regions. It is interesting that the incidence rates of ovarian cancer among Hispanic women in the San Diego area and in Dade County (white) were within the range of incidence rates found among non-Hispanic women.

Lung cancer's rank was the same for Hispanic and non-Hispanic women in a few geographic areas (the Chicago, San Diego, and San Francisco Bay areas and the state of California). In most other areas, the rank of lung cancer was higher among non-Hispanics than among Hispanic women.

The stomach did not appear within the top five sites of cancer for women in any geographic area.

Non-Hodgkin's lymphomas among Hispanic women appeared among the top five cancers only in the San Francisco Bay Area and New York City.

### Comparisons of Rates by Sex

Table 3 shows age-standardized rate ratios of cancer among Hispanic men, compared with Hispanic women, by geographic area. Hispanic men had higher incidence rates of cancer than did Hispanic women in all geographic regions, with the exception of



Table 3. Male/female standardized rate ratios\*

Cancer site or type	SRR												
	El Paso area	Lubbock area	Illinois	Chicago area	Dade County whites	Dade County blacks	New York City	Denver area	San Diego area	Los Angeles County	San Francisco Bay Area	New Mexico	Puerto Rico
Lung	2.75	3.65	1.90	1.80	4.57	5.25	3.65	2.70	2.37	2.29	1.70	2.03	2.18
Colon	1.09	3.27	0.99	1.05	1.13	1.60	1.21	1.16	0.61	1.50	1.33	1.31	0.88
Rectum	2.00	2.53	1.35	1.40	1.40	4.55	1.38	1.95	1.43	1.64	0.89	2.39	1.18
Stomach	1.60	2.01	1.70	1.73	1.82	4.55	1.81	1.17	2.13	1.78	2.42	2.05	1.63
Liver	1.90	2.87	2.04	1.65	2.16	1.20	5.70	1.17	2.36	3.14	3.11	2.45	1.59
Gallbladder	0.49	0.13	n/a	n/a	0.61	n/a	0.35	1.17	0.36	0.25	0.90	0.35	0.30
Oral cavity	3.32	1.04	2.04	2.26	3.77	8.81	4.60	1.86	3.68	3.07	3.09	6.33	3.23
Non-Hodgkin's lymphoma	1.57	2.34	1.09	1.13	1.39	4.60	1.51	1.36	1.62	1.54	1.43	1.54	1.00
Melanoma	1.21	0.65	0.78	0.85	1.39	n/a	1.55	1.94	2.00	0.96	0.64	0.83	1.18
All sites	1.13	1.08	0.87	0.88	1.27	1.35	1.42	1.36	1.37	1.25	1.28	1.37	1.08

\*n/a = data not available.

the state of Illinois and the Chicago area. The Illinois rates are largely driven by the Chicago rate. Men had a range from 8% higher rates in the Lubbock area and the Commonwealth of Puerto Rico to 42% higher in New York City. Hispanic men had higher rates of lung, stomach, liver, and oral cancers than did Hispanic women in all geographic regions.

Hispanic men in the Chicago area and the state of Illinois had 80% and 90% higher incidence rates of lung cancer than did Hispanic women in these regions, respectively. In Dade County, white Hispanic men were nearly 4.6 times more likely to have lung cancer than white Hispanic women. Black Hispanic men in Dade County were approximately 5.3 times more likely to have lung cancer than black Hispanic women.

For colon cancer, Hispanic men had higher rates than Hispanic women within most geographic regions; the exceptions were Illinois (where the male-to-female ratio was 0.99 [the SRR for the Chicago area was 1.05]), the San Diego area (where the SRR was 0.61), and Puerto Rico (where the SRR was 0.88). With the exception of the San Francisco Bay Area, Hispanic men had higher incidence rates of rectal cancer than did Hispanic women.

Stomach cancer was higher among Hispanic men than Hispanic women in all geographic areas. Black Hispanic men in Dade County were 1.5 times more likely to have stomach cancer than black Hispanic women. White Hispanic men in Dade County were 4.5 times more likely to develop stomach cancer than were white Hispanic women.

Liver cancer was higher among all groups of Hispanic men than Hispanic women in all geographic areas. The male/female SRR was the highest in New York City, where Hispanic men were more than five times more likely to have liver cancer than Hispanic women.

In all geographic areas, with the exception of the Denver area, gallbladder cancer rates were lower among Hispanic men than among Hispanic women. White Hispanic men in Dade County were 1.63 times less likely to have gallbladder cancer than were Dade County white Hispanic women. Hispanic men in the Lubbock area were more than seven times less likely to have gallbladder cancer than were Hispanic women in the same region.

Cancers of the oral cavity/pharynx displayed a predominance among Hispanic men, with the exception of Hispanic men in the Lubbock area. In the state of Illinois, Hispanic men were two times more likely to have oral cancers than Hispanic women. In the El Paso area, Dade County (whites), the San Diego area, Los Angeles County, the San Francisco Bay Area, and Puerto Rico, Hispanic males were between three and four times more likely to have oral cancers than non-Hispanic women. In Dade County, black Hispanic men were nearly nine times more likely to develop oral cancers than black Hispanic women.

Non-Hodgkin's lymphomas were higher among all populations of Hispanic men than Hispanic women, with the exception of Puerto Rico, where the SRR was equal to 1. Hispanic men in the Chicago area and the state of Illinois had 9% and 13% higher rates of non-Hodgkin's lymphoma, respectively, than did their Hispanic female counterparts. Hispanic men in New York City had an approximately 50% higher rate of non-Hodgkin's lymphoma than did the Hispanic women of the area. Black Hispanic men in Dade County had an SRR of 4.6, in relation to the black Hispanic women in Dade County.

Melanoma was more common among Hispanic men than among Hispanic women in the El Paso area, Dade County whites, New York City, the Denver area, the San Diego area, and Puerto Rico. It was less common among Hispanic men than Hispanic women in the Lubbock area, the Chicago area, the state of Illinois, the San Francisco Bay Area, and New Mexico. It was virtually the same among Hispanic men and women in Los Angeles County.

### Rate Ratios of Specific Sites of Cancer

This section describes the geographic variation in SRRs of cancers of specific sites associated with being Hispanic.

**Lung cancer.** For lung cancer (Fig. 1), incidence rates among Hispanic men were generally 60% of those among non-Hispanic men, as demonstrated by their lower SRRs. In the Miami and San Francisco Bay areas, the SRRs were close to (but below) 1.0, while in New Mexico and Puerto Rico, the SRRs were approximately 0.5. In all geographic areas, lung cancer rates were consistently lower among Hispanic women than among non-Hispanic women. The lowest rate ratios among women were



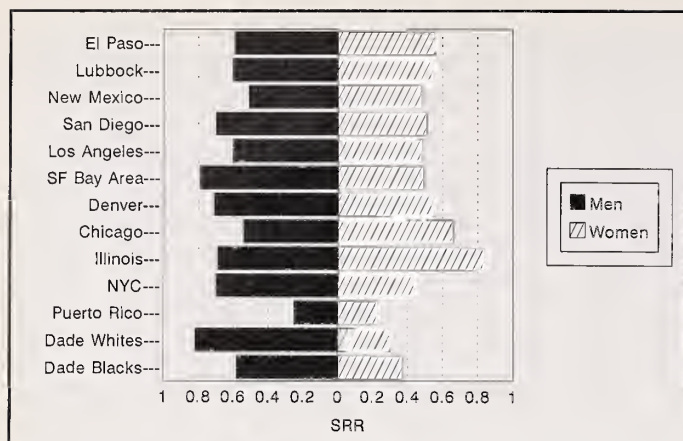


Fig. 1. Lung cancer. Standardized rate ratio (SRR) by geographical area and sex.

seen in Puerto Rico and among Dade County white and black Hispanics.

**Breast cancer.** There was a consistently lower rate of breast cancer (Fig. 2) among Hispanics; being approximately 70% that of non-Hispanics, with Hispanic women in Illinois having SRRs closer to 1.0. Black Hispanics in Dade County had 84% of the rate of black non-Hispanic women. Hispanic women in New York City, Puerto Rico, the San Diego area, and Los Angeles County had slightly less than 60% of the rate of non-Hispanic women, and Hispanic women in the Lubbock area had slightly less than 50%.

**Prostate cancer.** Hispanic men generally had rates of prostate cancer (Fig. 3) that were 80% as high as those in non-Hispanics. In several areas (the El Paso area, New York City, Los Angeles County, and Dade County [whites]), the SRR of prostate cancer was near the null value of the SRR, i.e., 1.0, signifying that the rates were equal among both groups. Among Dade County black Hispanics, the SRR of prostate cancer rates associated with being Hispanic was low because of high rates of prostate cancer among black non-Hispanics. Hispanic men in the Lubbock area had lower rates of prostate cancer than non-Hispanic men in that geographic area.

**Colon and rectal cancer.** The geographic distribution of SRRs for both colon and rectal cancers are similar, with Hispanic men averaging slightly more than one half the rates of non-Hispanics. The SRR for men in Puerto Rico (versus the U.S. white male population) was the lowest of all areas. The SRRs for New York City Hispanics, who are more likely to be of Puerto Rican origin, were relatively the same as those for Puerto Rican men and women. In the Chicago area and the state of Illinois, the SRRs were closer to 1.0 than in Puerto Rico or in New York City.

Rectal cancer rates among Hispanic men were 50%-70% of those among non-Hispanics, with Puerto Ricans having the lowest SRRs. Hispanic women had lower rates of colon and rectal cancers than non-Hispanic women; i.e., the former had rates that were 60%-80% as high for colon and rectal cancers. The lowest rate ratios were observed among Dade County black Hispanic women and Hispanic women in the Lubbock area.

**Stomach cancer.** Stomach cancer rates and ratios (Fig. 4) varied considerably by geographic area. Among men, the SRRs

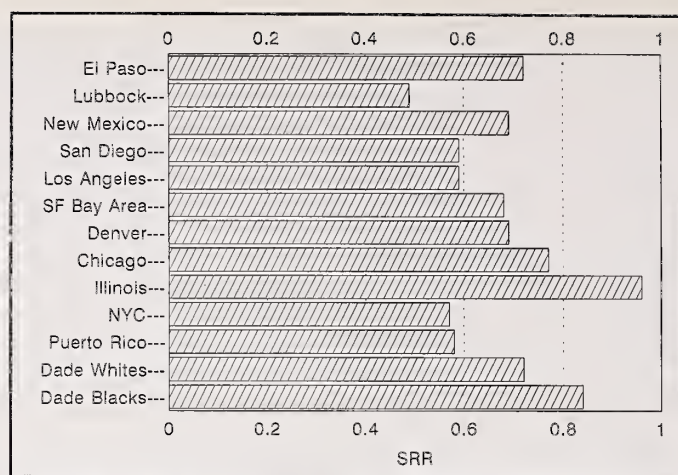


Fig. 2. Breast cancer. Standardized rate ratio (SRR) by geographical area.

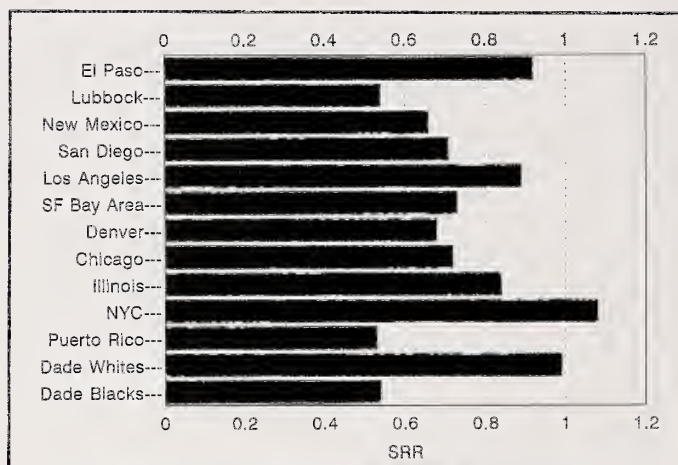


Fig. 3. Prostate cancer. Standardized rate ratio (SRR) by geographical area.

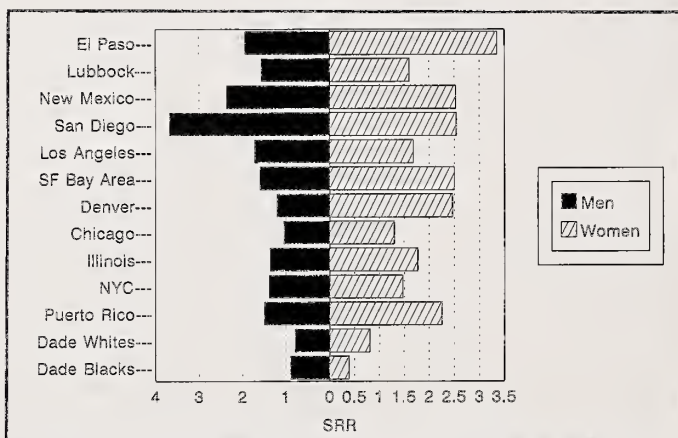


Fig. 4. Stomach cancer. Standardized rate ratio (SRR) by geographical area and sex.

among Dade County white and black Hispanics were less than 1.0. The highest SRRs of stomach cancer associated with being Hispanic were found in the San Diego area and in New Mexico. Among Hispanic women, the highest SRRs were found in the El Paso area. Among females, the Miami area was the only geographic region where the SRRs of stomach cancer were



lower among Hispanics than non-Hispanics. This was true for both the white and black Hispanics. With the exception of Dade County, stomach cancer rates were consistently higher across all geographic areas among Hispanic women.

**Gallbladder cancer.** These analyses showed that the SRRs for gallbladder cancer (Fig. 5) were greater than 1.0 for both Hispanic men and women in all geographic areas where data were available. Among Hispanic males, the highest SRRs were in New Mexico, the San Diego area, and the Denver area. Among Hispanic females, the highest SRRs were in the Lubbock and El Paso areas, New Mexico, and the San Diego area. Hispanic men generally had at least a 50% higher rate than non-Hispanics, except in New York City, the Lubbock area, and Puerto Rico. The SRRs of gallbladder cancer among Hispanic women were even more elevated, with the El Paso and Lubbock areas, New Mexico, and the San Diego area having SRRs of 4.0 or greater. The highest SRRs among Hispanic women were found in the El Paso and Lubbock areas, New Mexico, the San Diego area, and Dade County (black) Hispanics. The lowest SRRs of gallbladder cancer among Hispanic women were found in the San Francisco Bay Area.

**Liver cancer.** The liver (Fig. 6) was a cancer site that was elevated in Hispanic men in most regions. The SRRs ranged from 0.63 for Dade County black Hispanics to 4.46 in the Lubbock area. However, in the Denver and Chicago areas, there were virtually no differences between the incidence of liver cancer between Hispanic and non-Hispanic men. Liver cancer was also elevated among Hispanic women in all regions, with rates ranging from 1.38 in the Denver area to 3.31 in the El Paso area.

**Cancer of the uterine cervix.** Cervical cancer (Fig. 7) was higher among Hispanic women than among non-Hispanics in most geographic areas, with SRRs indicating nearly threefold elevated risks. The highest SRRs of cervical cancer associated with being Hispanic were found in New York City, Los Angeles County, and the Lubbock, El Paso, San Diego, and San Francisco Bay areas. The lowest SRRs of cervical cancer were found in Dade County (black) Hispanics. However, this observation was largely due to the higher rates among black non-Hispanic women living in Dade County. Despite this apparent increase in

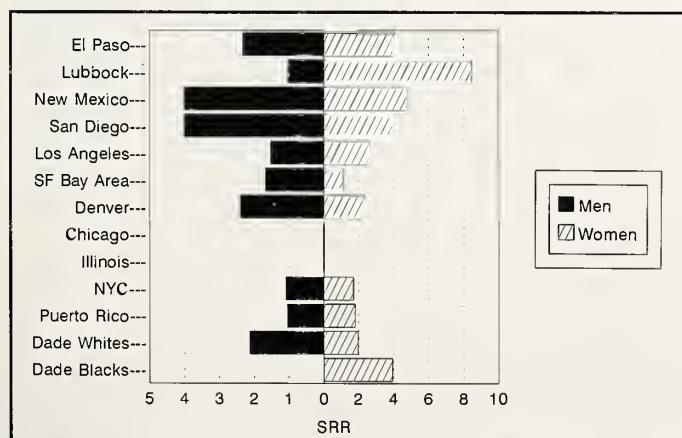


Fig. 5. Gallbladder cancer. Standardized rate ratio (SRR) by geographical area and sex.

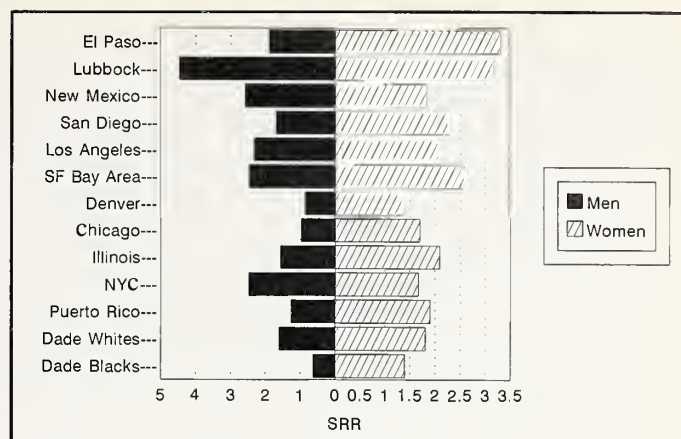


Fig. 6. Liver cancer. Standardized rate ratio (SRR) by geographical area and sex.

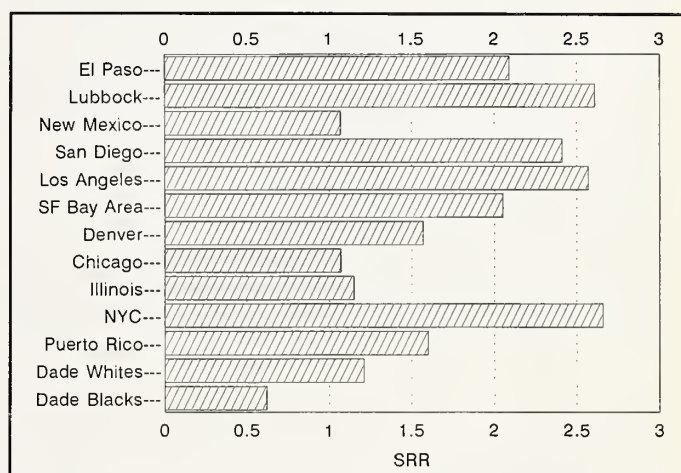


Fig. 7. Cancer of the uterine cervix. Standardized rate ratio (SRR) by geographical area.

risk, Hispanic women in New Mexico, the Chicago area, and Illinois did not show an elevated SRR.

**Endometrial/uterine corpus cancer.** Endometrial cancer occurred in Hispanic women at about 75% of the rate seen in non-Hispanic women, except in Illinois and New York City. In those areas, SRRs were equal to or marginally greater than 1.0. The lowest SRRs were in New Mexico, Puerto Rico, and Los Angeles County, where the SRRs were less than 0.60.

**Ovarian cancer.** Hispanic women showed consistently lower rates of ovarian cancer, with rates that were 75% as high as those among non-Hispanic women. Hispanics from the state of Illinois and from the Lubbock area, however, had SRRs of ovarian cancer that were slightly greater than those in non-Hispanic women in the same areas. In Dade County, the SRRs for both white Hispanics and black Hispanics were the same.

**Non-Hodgkin's lymphoma.** Hispanic men had about 75% of the incidence rate of non-Hodgkin's lymphoma as non-Hispanic men. The only exception was among Dade County black Hispanics, who had substantially higher rates (SRR = 1.6) than black non-Hispanic men. Hispanic women also had approximately 75% the incidence rate of non-Hispanic women. However, Hispanic women from the San Francisco Bay Area



and from the state of Illinois had SRRs that were marginally greater than 1.0.

**Melanoma.** Melanoma occurred among Hispanic men at one tenth to one fourth the rate of non-Hispanic men. Among black Dade County Hispanics, there was a nonsignificantly higher rate of melanoma among black Hispanic men than among black non-Hispanic men because of lower rates in black non-Hispanic men.

**Oral cancers.** Among Hispanic men, oral cancers occurred at approximately 70% of the rate of non-Hispanic men. In the Lubbock area, this ratio was substantially lower, while Hispanic men from New York City had a 60% higher rate of oral cancer than non-Hispanic men. Oral cancers were consistently lower in Hispanic women than in non-Hispanic women.

**All sites combined.** Hispanic women had lower SRRs for all sites combined, at approximately 0.9 (Fig. 8). There was very little difference in area-specific SRRs, with the exception of Illinois, where the SRR was slightly greater than 1.0. This latter excess is reflected in slightly higher incidence rates among Hispanic females for cancers of the ovary, cervix, rectum, and endometrium and for non-Hodgkin's lymphoma and considerably higher incidence rates for stomach and liver cancers relative to non-Hispanic women in the region.

Hispanic men of all geographic regions had SRRs between 0.5 and 0.9. The lowest SRRs for males were in Puerto Rico, with estimates of approximately 0.5, compared to the U.S. white male population. The elevated SRR among Hispanic females in Illinois was not found for Hispanic males in the same area.

## Discussion

### All Sites Combined

Hispanic men and women showed incidence rates for all cancer sites combined consistently lower than those seen in non-Hispanic men and women. This is an effect of low incidence rates among Hispanics of major cancers such as lung, breast, prostate, ovarian, endometrial, colon, rectum, and melanoma. However, assuming that the incidence rates are valid, this may be due to an amalgamation of genetics and perhaps less exposure to risk factors for some cancers. However, a separate issue may be that Hispanics are not well represented in registry

reports and, therefore, are often misclassified, resulting in underreporting of some cancers.

### Lung and Oral Cancers

Our data on lung cancer are consistent with many reports of low rates of lung cancer among Hispanic men (9) and women (10,11). Some studies have found higher mortality rates for lung cancer (12) and oral cancer (9) among Puerto Rican men than other Hispanic men, which could be viewed as consistent with the incidence data presented for New York City. While the overall prevalence of smoking among Hispanics has been reported in some studies to be lower than that among non-Hispanic whites (13-16) and higher in others (17,18), the bulk of evidence suggests higher rates of smoking among Hispanic men and lower rates of smoking among Hispanic women than among non-Hispanics (19), with variations by nationality and location. The Hispanic Health and Nutrition Examination Survey (HHANES) study found that the highest smoking rates were among Cuban-American men, followed by Mexican-American, Puerto Rican, and white non-Hispanic men. In contrast, the National Health Interview Survey found that the prevalence of smoking is lower in Latinos and that rates were falling for Hispanic men and rising for Hispanic women (20). Preliminary base-line survey data from the National Hispanic Leadership Initiative on Cancer (NHLIC) on tobacco use (1994, unpublished results) have shown that the percentage of Hispanic/Latino men who smoke varied from a high of 30% in San Antonio, Tex., to a low of 17% in San Diego. Contrary to the findings in the HHANES study, smoking rates were found to be highest among Mexican-American men in San Antonio and Laredo, Tex., followed by Puerto Ricans in New York and Cuban-American men in Miami. Smoking rates were lower among Hispanic/Latina women, with women in Brownsville, Tex., and San Francisco showing the lowest rates (7.61% and 8.84%, respectively). Tobacco use among Hispanic women was most common in New York, where 20.3% reported smoking. These differences in smoking prevalence between Hispanic groups are consistent with the regional differences in lung cancer rates between Dade County white Hispanics (predominantly of Cuban origin), southern California and Texas (predominantly Mexican-American), and Puerto Rico.

Many studies, including HHANES, showed that, among Hispanics, acculturation and language use were specifically associated with the consumption of alcohol as well as smoking (21-23). If the low rates of oral cancer among Hispanic women are related to lower levels of both smoking and alcohol consumption and the lower prevalence of smoking among Hispanic women is reflected in lower incidence rates of lung cancer, then the implementation of programs that reinforce these habits may prevent a rise in rates of these cancers.

### Breast Cancer

Unlike the uterine cervix, a site of cancer often thought of as associated with Hispanic women, the incidence rates of breast cancer among Hispanic women are lower than those among white non-Hispanic women. Our analyses are consistent with those of Thomas and Karagas (24), who found lower incidence rates of breast cancer among Hispanic women, possibly due to

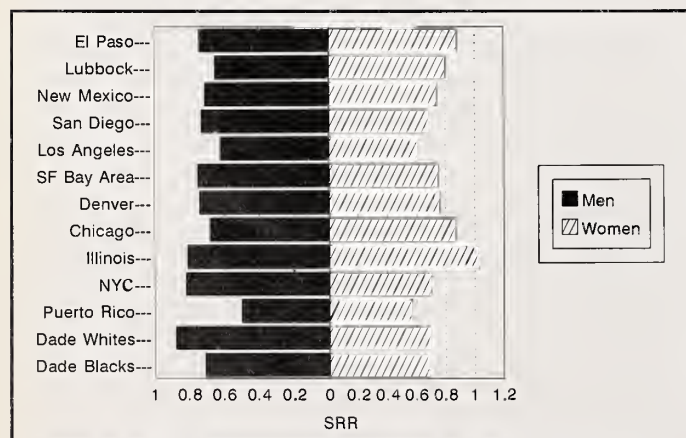


Fig. 8. All sites. Standardized rate ratio (SRR) by geographical area and sex.



protective factors such as low fat intake. Others (25,26) have found little or no association between fat intake and breast cancer.

Buchanan et al. (27) looked at parity and breast cancer rates in a Mexican-American population and found no association.

Another study (28) has focused on the association between socioeconomic status and incidence of breast cancer and found that socioeconomic status is directly related to risk. There also seems to be a difference in risk associated with race versus ethnicity, as seen in Dade County, where incidence rates for breast cancer among white Hispanic women are lower than among black Hispanic women. This implies that looking at "Hispanic" versus "non-Hispanic" is not sufficient and may obscure opportunities for etiologic and intervention research.

### **Prostate Cancer**

Prostate cancer has many possible causes, but few definitive risk factors. The incidence of latent prostate cancer is similar around the world, yet the incidence of clinically manifest prostate cancer varies tremendously from area to area. It is unknown what makes some prostate cancers definitively progress while others do not (29). Interactions between genetic and environmental determinants are likely to underlie the divergence in prostate cancer occurrence among racial and ethnic groups.

Results from the most recent National Cancer Data Base (30) report on prostate cancer showed that Hispanics accounted for 2.5% of all prostate cancers, at least in their subset of hospitals. With the increases in incidence and mortality that are occurring nationally, prostate cancer remains a concern for Hispanic men.

### **Colon and Rectal Cancer**

Studies of colon and rectal cancer have repeatedly found lower rates among Hispanics relative to white non-Hispanics. Thomas and Karagas (24) reported that rates of colon cancer increased rapidly for successive generations of Americans from Japan, China, and Mexico and presumed it would be true for Puerto Ricans living in the United States. They further reported that the rates rose more rapidly among men than among women. In a study in Los Angeles, Mack et al. (28) found that Hispanics born in the United States lose their lower rates of colon cancer and acquire those of United States-born residents and that older migrants assumed U.S. risks to a lesser extent than persons who migrated as children. The fact that both Hispanic men and women had SRRs equal to or less than 1 for colon cancer in all geographic regions illustrates that the incidence of colon cancer has not generally reached non-Hispanic levels.

Colon and rectal cancers generally have shown a positive association between disease incidence and diets high in animal fat and low in fiber. Cancers that have been inversely related to low fat, high fiber, and high vitamin A intake tend to occur less frequently among Hispanics. Haffner et al. (31) found that Mexican-American women living in low-income areas had diets characterized by higher intakes of foods with cholesterol than either Anglos or Mexican-Americans living in middle or upper income areas but that increases in socioeconomic status corresponded with lower levels of fat intake. Paradoxically, Mexican-American men were shown to increase their cholesterol intake with increasing socioeconomic status levels, consuming a much greater atherogenic diet. While this does not

necessarily explain the lower levels of colon and rectal cancers among Mexican-Americans, it is consistent with some of the sex differences and may add support to findings showing increases in cancer incidence for succeeding generations.

### **Stomach Cancer**

These data show that the incidence of stomach cancer is higher among Hispanic men and women than among non-Hispanics in most of the geographic regions included. The lower rates are in accord with previous studies showing elevated risks of stomach cancer for several different Hispanic groups (32-34). Wiggins et al. (35) reported decreases in rates of mortality from stomach cancer from 1958 through 1962 among both Hispanic and non-Hispanic populations of New Mexico. This was consistent with SEER findings among black and white men and women. However, the finding by Wiggins et al. of constant incidence over time was in contrast with the findings in SEER, which reported decreases in stomach cancer incidence for both black and white men and women.

The lower SRRs of stomach cancer among Hispanics in Dade County is probably a reflection of the demographics of the area. Hispanics in Dade County are predominantly Cuban and are of higher socioeconomic status than many other Hispanic groups. Only 13% of Miami Cubans are below the poverty level—a risk factor inversely related to the incidence of stomach cancer—versus 42% of Puerto Ricans (36) and 26% of Mexicans (35,37,38).

### **Gallbladder Cancer**

Data on gallbladder cancers in Hispanic populations show a higher incidence and mortality compared with white non-Hispanics. As a result, cancer of the gallbladder has long been cited as being an important cancer for Hispanics (39,40).

There appears to be some variance in the incidence rates between sexes. For example, Hispanic women were more likely to develop gallbladder cancer than Hispanic men. In fact, 5% of all cancers among women in Latin American occur in the gallbladder (41). A Mexico City autopsy series indicates that gallbladder cancer is a common malignant neoplasm in Mexican women. Studies done in California (42) also showed that the incidence of gallbladder cancer was higher in Hispanic women than in non-Hispanic white women. This is consistent with the findings of Mack et al. (28), who observed more extreme variations in risk of gallbladder cancer among Hispanic women in Los Angeles than in non-Hispanic women. In Hispanics, as in other white Americans, risk is associated with low socioeconomic status.

### **Liver Cancer**

The higher SRRs of liver cancer in both Hispanic men and women may be attributed to increased exposures to known risk factors. Of all known or suspected etiologic agents for cancer, perhaps the most potent is aflatoxin (43). Aflatoxins are found naturally in areas of high humidity with weather conditions similar to those of several of the areas included in these analyses. In addition, aflatoxins are found on substrates of grains and beans, often parts of traditional "Hispanic" diets.



Trapido et al. (7) have also speculated that the increase in Dade County Hispanics could be due to increases in non-A, non-B cryptogenic cirrhosis observed among Cubans in Miami. Other research has shown that hepatitis B virus and hepatitis C virus are significant etiologic agents for liver cancer (44,45), and some groups of Hispanics have higher rates of hepatitis B and C (46).

### Cancer of the Uterine Cervix

Among Hispanics, rates are higher for Mexican-Americans and Puerto Ricans compared with Cuban-Americans, whose rates are similar to those of non-Hispanic whites (47). This is evident in the higher incidence rates found in the northeast and southwest United States, which have larger percentages of Mexicans and Puerto Ricans. Previous studies (48) found that Mexicans and Puerto Ricans in Illinois had a higher risk for cervical cancer than other Hispanic women. The variation in incidence rates among women of different ethnic origins was also observed by Becker et al. (49), who found strong differences in age-adjusted rates and in age-specific patterns for cervical cancer among three ethnic groups in New Mexico. American Indians had the highest incidence, Hispanics had an intermediate rate, and non-Hispanic whites had the lowest incidence.

Although the specific cause of cervical cancer is unknown, studies consistently support an etiologic link between sexually transmitted diseases, specifically human papillomaviruses (HPVs) and cervical cancer (50). This is consistent with the results of Schiffman et al. (51), who observed a strong causal relationship between HPV infection and cervical cancer. These results are further supported by ethnic differences in the prevalence of cervical HPV infection and viral subtypes at the time of screening (52).

### Endometrial/Uterine Corpus Cancer

Mack et al. (28) observed that the risk for cancer of the endometrium in Los Angeles Mexicans was nearly as low as the risk in South America. This observation is consistent with the findings of Savitz (39), who noted that certain cancers (i.e., cancer of the uterine corpus) were less common among persons with Spanish surnames compared with other whites. Conversely, Hispanics from the Caribbean living in Los Angeles, in contrast to the Cubans living in Cuba, tended to have risks for endometrial cancer comparable to those of non-Hispanics. These patterns are suggestive of environmental factors that work late in life and may reflect the surrounding cultural milieu rather than long-held cultural practices.

### Ovarian Cancer

The age-adjusted incidence of and mortality rates from ovarian cancer are higher among white than non-white populations (53). While the cause of ovarian cancer remains largely unknown, some factors may explain the differences in incidence between the Hispanic and non-Hispanic populations in these analyses. Researchers have described an inverse relationship between socioeconomic status and ovarian cancer. In addition, studies have reported that Hispanic women have more children

earlier in life (54,55). Similar to the observations of breast cancer risk, parity is inversely related to ovarian cancer risk.

### Non-Hodgkin's Lymphoma

The incidence of non-Hodgkin's lymphoma among white men in the United States was 6.9/100 000 person-years in 1947-1950 and 17.4 in 1984-1988 (56). Incidence rates for non-Hodgkin's lymphoma have increased steadily at 3%-4% yearly since the early 1970s, more rapidly than for all other cancers except melanoma of the skin and lung cancer among women (57). However, the impact of acquired immunodeficiency syndrome (AIDS) during the 1980s seems to be responsible for increased incidence rates among young and middle-aged persons, as is illustrated by our rankings of the top sites. The association of malignant lymphoma with AIDS has been recognized since early in the human immunodeficiency virus epidemic (58). The lower rates among women are consistent with the literature that shows lower AIDS incidence rates among women.

### Melanoma

The incidence of melanoma is higher among white non-Hispanics (59,60), followed by Hispanics of either race and then black non-Hispanics. Most studies have grouped Hispanics in white or black population categories when reporting differences in skin cancer incidence, so the focus has been between "blacks" and "whites." However, various researchers have re-evaluated skin cancer data and separated Hispanics and Native-Americans from the Caucasians and African-Americans and have shown that brown-skinned individuals have a lower incidence of skin cancer than fair-skinned individuals but have a slightly higher incidence than blacks (61).

Recent studies have shown that the occurrence of melanoma within the southwestern U.S. Hispanic population and Puerto Rico is five to six times lower than that among non-Hispanic Caucasians (62,63). Studies have shown that malignant melanoma among Hispanics in the southeastern United States may have an improved prognosis compared with that among whites in this geographic area (60,64,65).

Redefining the Hispanic/Latino classifications to better represent their varied ethnic/genetic constitution could be critical in this instance. One possibility is to include a skin type classification in conjunction with information on ethnic background (60). As new tests for genetic susceptibility are developed, their application will be important in understanding the causes and, thus, the prevention of cutaneous melanoma among the different ethnic populations.

### Data Limitations

This article presented a synthesis of the epidemiology of cancer among Hispanics, emphasizing cancer incidence data. The process of compiling information reinforced our concerns about data availability, as well as their limitations and quality. The problems associated with evaluating and interpreting cancer data relevant to Hispanics are summarized below, and recommendations for corrective actions/policies are made.

**Problems with incidence data.** Incidence data have not been routinely available for Hispanics from many geographic areas,



and different time periods have been reported in registry publications. This is often compounded by a lag in reporting and publishing data, which has resulted in an abundance of "old" data. Furthermore, the incidence of various cancers changes over time. Many researchers have reported that the longer immigrants are in the United States, the more likely that certain cancer rates, like those for lung and breast cancers, change to reflect the rest of the population's rates. This lack of uniform reporting of time periods also makes trends difficult to assess. Finally, published cancer data seldom include measures of variance. This situation, for example, prevented variance estimates or confidence intervals from being included in the registry data presented above.

A shorter period between diagnosis and reporting is needed. (It will be required in the Centers for Disease Control and Prevention's new National Program of Cancer Registries.) Uniform time periods, which are adhered to and supported by researchers, should be established by governmental and funding organizations. Hospitals and other providers of cancer data need to be included in the decision-making processes in these matters, since the burdens associated with reporting requirements often fall on their staff. A standard set of items should be presented in published reports that would permit calculation of standard errors or confidence intervals.

**Problems with definitions.** Definitions of "Hispanic," "Latinos/Latinas," "Latins," and "white Hispanics" vary between registries. In addition, comparisons have been made to "non-Hispanics," "non-Latins," "Anglos," "whites," or "white non-Hispanics." Depending on the choice of terms, both the numerator (number of newly diagnosed cases) and the denominator (population) of an incidence rate of cancer will vary, which is likely to result in noncomparability region to region. Furthermore, the methods used and the personnel responsible for determining whether an individual is "Hispanic" may vary.

Uniform definitions and a standard methodology should be established for classifying individuals in registries, studies, reports, etc. Systems and definitions, such as those used by SEER or developed by the North American Association of Central Cancer Registries or adopted by the National Program of Cancer Registries, are possible solutions, but their use is unlikely to extend beyond central cancer registries. If census data are to be used, then the same definitions should be used in registries, hospitals, and laboratories and by agencies and researchers. Consideration should be given to adding variables that will help in such determinations, such as language spoken, and "maiden" name or mother's maiden name. A consensus conference should be organized by the National Institutes of Health, the Centers for Disease Control and Prevention, or other interested group(s) to review and develop definitions.

Definition concerns underlie the larger problem of collapsing heterogeneous groups into single categories. Ideally, this article should have been able to present information on cancer among Puerto Ricans living in Puerto Rico, New York, Miami, San Francisco, etc.; Mexican-Americans living in Texas, California, Miami, Denver, New Mexico, Chicago, etc.; Cubans living in Miami, New York City, San Francisco, etc.; and Nicaraguans, Salvadorans, and so forth. At each level—registry, census, university, hospital, or governmental agency—a process needs

to begin to collect, analyze, and present data not on "Hispanics" per se but on more homogeneous, better defined populations.

**Problems with age standardization, age-specific counts, and rates.** For the most part, data are consistently presented as directly standardized rates, using the 1970 U.S. standard million population. However, examination of standardized rates does not allow focusing on specific ages (e.g., women older than 50), which could be important for establishing intervention priorities (e.g., related to breast cancer screening). Furthermore, presentation of data in formats that are already standardized does not allow comparisons to other standards, such as those used by the World Health Organization and countries in Latin America.

Age-specific counts and denominators in the standard 18-category age groups (0-4, 5-9, 10-14, . . . 85+ years) should be presented, in addition to directly age-standardized rates.

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## Notes

<sup>1</sup>*Editor's note:* SEER is a set of geographically defined, population-based central tumor registries in the United States, operated by local nonprofit organizations under contract to the NCI. Each registry annually submits its cases to the NCI on a computer tape. These computer tapes are then edited by the NCI and made available for analysis.

<sup>2</sup>The Centers for disease Control and Prevention has made funds available that will enable states to create or enhance existing statewide registries and to produce cancer incidence reports to improve prevention and control activities.

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# Lung Cancer, Smoking Patterns, and Mutagen Sensitivity in Mexican-Americans

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**Background:** Mexican-Americans have lower age-adjusted lung cancer incidence rates than non-Hispanic whites and African-Americans. Since 87% of lung cancers are attributed to tobacco exposure, this difference could be explained partly by lower prevalence of cigarette smoking. However, only a fraction of exposed individuals will develop smoking-related cancer, and genetically determined differences in modulation of environmental exposures could also explain some of this ethnic risk differential in lung cancer incidence in the United States. However, little research on genetic susceptibility has been focused on Hispanic populations in the United States. **Methods:** We are conducting a case-control study of lung cancer in a high-risk group (African-Americans) and a low-risk group (Mexican-Americans) to evaluate ethnic differences in mutagen sensitivity by an in vitro assay that quantifies mutagen-induced chromosome breaks in short-term lymphocyte cultures. **Results:** In the 174 Mexican-Americans (67 lung cancer case patients and 107 control subjects) accrued to date, all measures of cigarette smoking (intensity, duration, nicotine and tar contents, depth of inhalation, and type of cigarette) were significant predictors of lung cancer risk. There were significantly higher risks associated with mutagen sensitivity (defined as  $\geq 1$  break/cell) for both former smokers (odds ratio [OR] = 4.5; 95% confidence interval [CI] = 0.9-21.9) and current smokers (OR = 2.6; 95% CI = 0.6-11.1). Mutagen sensitivity also appeared to be implicated in risk in patients who were less than 55 years old at diagnosis (OR = 15.0; 95% CI = 1.0-228.9) and in those with lower cigarette exposure (OR = 11.0; compared with an OR of 1.7 for the heaviest smokers). The overall OR for mutagen sensitivity adjusted for age, sex, and pack-years of smoking was 2.9 (95% CI = 0.8-9.9). Neither current smoking status nor years of exposure shifted the sensitivity profile of case patients and control subjects. **Conclusion:** Although this study showed higher percentages of nonsmokers among Mexican-Americans than our previously reported data for African-Americans, the Mexican-American case patients were heavier smokers than the African-American case patients. The prevalence of mutagen sensitivity for Mexican-Americans was 64.1% in case patients and 26.2% in control subjects. In African-Americans, mutagen sensitivity was previously reported to be 55.3% in case patients and 24.6% in control subjects. These preliminary data do not support our a priori hypothesis that a lower prevalence of mutagen sensitivity in Mexican-Americans would account

for the lower incidence of lung cancer. Mutagen sensitivity, however, is only one of an array of potential susceptibility markers that we are evaluating in this unique population. [Monogr Natl Cancer Inst 18:29-33, 1995]

There is a rapidly expanding body of literature on the concept of genetically determined interindividual susceptibility to carcinogenesis. Eighty-seven percent of lung cancers are attributed to tobacco exposure, and the relative risk of lung cancer in current smokers is up to 20-fold higher than that in never smokers (1). However, only a fraction of exposed individuals actually will develop smoking-related cancers. Ianzuzi and Miller (2) maintain that "no organ system is more dependent on the interaction of the environment and heredity than the lungs."

Genetically determined differences in modulation of environmental exposures may partially explain the large ethnic differences in cancer incidence and mortality in the United States. Numerous U.S. and international lung cancer studies have explored the role of gene-environmental interactions in U.S. whites, African-Americans, Europeans, and Japanese. However, very little research has been focused on Hispanic populations in general and Mexican-Americans in particular. Texas presents an ideal population in which to study Mexican-Americans, since 25% of the population of Texas is Hispanic, 90% of whom are of Mexican origin (3).

There are substantial ethnic differences in lung cancer risk in Texas, where the age-adjusted lung cancer incidence rates for Hispanic men for 1976-1985 (based on data available for 25% of the total state population) were only 58% of the rates for non-Hispanic whites and 44% of the rates for blacks (4). For Hispanic women, the comparable age-adjusted rates were 58% of those for non-Hispanic white women and 71% of those for black women.

Variations in cigarette-smoking prevalence are the most likely explanation for these ethnic differences in cancer incidence. In fact, survey data clearly demonstrate significantly different

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See "Note" section following "References."



patterns of cigarette smoking among men and women and among different ethnic groups. National and regional data for 1985 documented that the prevalence of current smoking among Hispanic men (28.5%) was comparable to that among non-Hispanic white men (31.6%) but lower than that among black men (39.7%). Hispanic women show consistently lower prevalences of cigarette smoking (5-7). Furthermore, Hispanic smokers of both sexes tend to smoke fewer cigarettes per day than their black and white counterparts (8,9). However, lung cancer incidence is increasing in Denver and New Mexico Hispanics, suggesting that the smoking patterns have shifted toward greater cigarette consumption (10,11).

To explore the role of genetically determined predisposition to lung cancer, we are conducting a case-control study in a high-risk group (African-Americans) and a low-risk group (Mexican-Americans), incorporating markers of cancer susceptibility. One such marker is mutagen sensitivity, which we measure by an *in vitro* cytogenetic assay developed by Hsu et al. (12). In this assay, *in vitro* mutagen sensitivity is measured in short-term peripheral lymphocyte cultures by quantifying the number of chromatid breaks induced by exposing the cultures to bleomycin, a radiomimetic agent, for 5 hours. This assay has been shown to be reproducible and to have low intraindividual variation. In two case-control studies (13,14), we demonstrated that sensitivity as determined by the assay and defined as  $\geq 1$  break/cell is an independent risk factor for cancers of the upper aerodigestive tract after adjustment for tobacco and alcohol consumption (13,14) and also a predictor of second malignancies (15). Recently, we (16) reported preliminary data on mutagen sensitivity as a risk factor for lung cancer in African-Americans accrued in this ongoing case-control study and demonstrated that mutagen sensitivity was a significant predictor of lung cancer risk in African-Americans (odds ratio [OR] = 3.7; 95% confidence interval [CI] = 1.4-9.4). We now present data on smoking patterns and mutagen sensitivity as risk factors for lung cancer in 174 Mexican-Americans identified in the same case-control study.

## Subjects and Methods

Case patients were those patients with newly diagnosed, histologically confirmed lung cancer who described themselves as being of Mexican-American origin. Patients who had not been treated previously with radiotherapy or chemotherapy were recruited from The University of Texas M. D. Anderson Cancer Center and from county, community, and U.S. Department of Veterans Affairs hospitals in the Houston and San Antonio areas. There were no age, histologic, or stage restrictions.

Control subjects were Mexican-Americans without a history of cancer. They were recruited from community centers, cancer-screening programs, churches, and employee groups in both Houston and San Antonio. The control subjects were frequency matched to the case patients by sex and age ( $\pm 5$  years) in a ratio of two control subjects to one case patient.

Trained, bilingual interviewers/phlebotomists conducted the structured personal interviews and drew 20 mL of blood into heparinized tubes for cytogenetic and molecular genetic analyses. The questionnaire used was translated into Spanish and back-translated by The Department of Mexican Studies at the University of Houston. Study participants could choose English or Spanish for the interview. Data were collected on sociodemographic characteristics, recent and prior history of smoking, and other lifestyle habits.

The methodology for the mutagen sensitivity assay was described previously (17). Briefly, peripheral blood lymphocytes were cultured in RPMI-1640 medium supplemented with 15% fetal bovine serum. On the 3rd day of incubation, bleomycin (0.03 U/mL) was added for the last 5 hours of culture. One hour

before the end of the 72-hour culture, Colcemid (0.04  $\mu$ g/mL) was added to arrest the cells in metaphase. Whenever possible, 50 metaphases per sample were evaluated to calculate the frequency of bleomycin-induced chromatid breaks, and breakage was averaged to the number of breaks per cell. Individuals who exhibited  $\geq 1$  break/cell were considered to be mutagen sensitive.

Chi-square tests and chi-square tests for linear trend were used for demographic variables. Differences in continuous variables were evaluated by Student's *t* test. ORs and 95% CIs were calculated according to demographic, smoking, and mutagen sensitivity variables (18). Mutagen sensitivity was analyzed as a continuous variable and also dichotomized at the level of 1 break/cell. Logistic regression was used to estimate risks, which were adjusted for multiple factors. All variables that were statistically significant in the univariate analysis were included in the first logistic model. For the final model reported here, we excluded variables and interaction terms that were not statistically significant in the preliminary modeling. The 95% CIs for the adjusted ORs were calculated by using the estimated logistic coefficient and the corresponding standard error.

## Results

This report is based on data from 67 Mexican-American lung cancer case patients (48 men and 19 women) and 107 control subjects (68 men and 39 women). Table 1 shows the distribution of case patients and control subjects by selected sociodemographic variables. Since a frequency-matching approach to control selection is being used (with a planned ratio of 2:1 controls to cases) and the study is still ongoing, perfect matching has not yet been achieved. The mean age was 63.8 years for both case patients and control subjects. Male case patients were an average of 1.5 years older and female case patients an average of 3 years younger than their respective control subjects. The educational level of case patients and control subjects was similar; 44.3% of case patients and 47.9% of control subjects reported less than an elementary school education. More control subjects than case patients (45.7% versus 31.7%) reported an annual

Table 1. Distribution of select demographic variables by case-control status

	Case patients *	Control subjects*	P
Total	67	107	
Sex			
Male	48 (71.6)	68 (63.6)	.27
Female	19 (28.4)	39 (36.4)	
Mean age, y $\pm$ SD	63.8 $\pm$ 10.6	63.8 $\pm$ 12.2	.97
Education, y			
$\leq 6$	27 (44.3)	46 (47.9)	.67
7-9	9 (14.8)	14 (14.6)	
10-12	17 (27.9)	24 (25.0)	
$\geq 13$	8 (13.1)	12 (12.5)	
Annual income, \$			
<9000	19 (31.7)	43 (45.7)	.03
9000-19 999	19 (31.7)	33 (35.1)	
20 000-29 999	13 (21.7)	10 (10.6)	
30 000-39 999	4 (6.7)	3 (3.2)	
$\geq 40 000$	5 (8.3)	5 (5.3)	
Household size, No. of inhabitants			
1	16 (25.8)	49 (49.0)	.08
2	25 (40.3)	24 (24.0)	
3	8 (12.9)	14 (14.0)	
4	9 (14.5)	4 (4.0)	
$\geq 5$	4 (6.5)	9 (9.0)	

\*Number of case patients and control subjects may differ because of missing data. Unless otherwise specified, values in column = number of individuals (%).



household income of less than \$9000. In addition, control subjects tended to come from smaller households than the case patients; 49% of the control subjects lived alone compared with 25.8% of the case patients.

Predictably, there were significant differences in smoking practices between the case patients and the control subjects. More than 83% of the case patients had ever smoked, compared with 51% of the control subjects ( $P < .001$ ). The overall mean age of smoking initiation was similar for case patients and control subjects (18.7 years versus 20.3 years;  $P = .39$ ), but male case patients were an average of 2 years older and female case patients were approximately 6.5 years younger than their respective control subjects when they started smoking (males: 17.5 years versus 15.9 years, respectively,  $P = .30$ ; females: 23.8 years versus 30.3 years, respectively,  $P = .25$ ). The means for lifetime cigarette pack-years were significantly higher for case patients than for control subjects (53.3 pack-years versus 22.7 pack-years, respectively;  $P < .0001$ ), with twofold differences for both sexes (data not shown).

Table 2 presents univariate ORs for smoking status and select tobacco practices. Former smokers were defined as ex-smokers who had quit more than 1 year previously. More recent quitters were included in the current-smoking category. There were significantly elevated risks associated with both former smoking (OR = 5.8; 95% CI = 2.5-13.5) and current smoking (OR = 4.1;

95% CI = 1.8-9.4). Risk increased with reported pack-years of exposure, with a risk estimate of 11.8 (95% CI = 4.7-30.5) for the most heavily exposed stratum ( $P$  for trend  $< .001$ ). There were significantly increased risks associated with smoking cigarettes of all tar and nicotine contents. The highest risks were for smokers of cigarettes with the greatest tar content (OR = 9.5), compared with an OR of 5.4 for smokers of cigarettes with the highest nicotine content. From the self-reported data, we noted an increased risk with increasing self-perceived depth of inhalation (OR = 6.4 for those reporting that they inhaled "deeply into the chest"). The risk for smoking king-sized cigarettes (OR = 8.1; 95% CI = 2.6-25.3) was almost twice that for smoking regular-sized cigarettes (OR = 4.9; 95% CI = 2.2-10.8). Smoking filtered or menthol cigarettes was associated with a nonsignificant lower risk than smoking unfiltered or non-menthol cigarettes (ORs = 0.4 and 0.6, respectively; data not shown).

There was an increased risk of borderline statistical significance for those former smokers who quit at age 50 or older, compared with those who quit before age 50 (OR = 3.3). Very few subjects reported using tobacco products other than cigarettes: One case patient reported chewing tobacco, two case patients and two control subjects reported smoking cigars, and none reported dipping snuff.

Table 3 analyzes in more detail the smoking habits of the male and female control groups. Of those currently smoking, 82% of the men and all the women did not complete high school. The men had initiated smoking significantly earlier in life (15.1 years) than the women did (31.7 years,  $P = .01$ ). Women smoked significantly fewer cigarettes per day than men (6.4 versus 15.2). Men tended to prefer regular-sized cigarettes, but women showed nearly equal preference for both regular-

**Table 2.** Risk estimates for select tobacco practices by case-control status

	No. (%)		OR (95% CI)
	Case patients*	Control subjects*	
Smoking status			
Never	11 (16.4)	52 (48.6)	1.0
Former	28 (41.8)	23 (21.5)	5.8 (2.5-13.5)
Current	28 (41.8)	32 (29.9)	4.1 (1.8-9.4)
Pack-years of exposure			
None	11 (16.4)	52 (50.4)	1.0
<25	11 (16.4)	31 (30.6)	1.7 (0.6-4.8)
≥25	45 (67.2)	18 (17.8)	11.8 (4.7-30.5)
Tar content, mg†			
≤14	14 (34.1)	13 (28.3)	5.1 (1.9-13.8)
15-19	19 (46.3)	29 (63.0)	3.1 (1.4-8.0)
≥20	8 (19.5)	4 (8.7)	9.5 (2.4-37.0)
Nicotine content, mg†			
≤0.9	14 (34.1)	12 (26.1)	5.5 (2.0-15.1)
1.0-1.2	19 (42.4)	27 (58.7)	3.3 (1.3-8.1)
1.3-1.6	8 (19.5)	7 (15.2)	5.4 (1.6-18.0)
Extent inhaled†			
Did not inhale	1 (1.8)	3 (5.5)	1.6 (0.1-16.6)
Only into mouth or throat	20 (36.4)	27 (49.1)	3.5 (1.5-8.4)
Deeply into chest	34 (61.8)	25 (45.5)	6.4 (2.8-14.8)
Cigarette size†			
Regular	36 (66.7)	35 (66.0)	4.9 (2.2-10.8)
King	12 (22.2)	7 (13.2)	8.1 (2.6-25.3)
100/120 mm	6 (11.1)	11 (20.8)	2.8 (0.8-8.5)
Age stopped smoking, y‡			
<50	7 (21.9)	11 (47.8)	1.0
≥50	25 (78.1)	12 (52.2)	3.3 (1.0-10.6)

\*Number of case patients and control subjects may differ because of missing data.

†Never smoked was referent.

‡Includes recent quitters.

**Table 3.** Cigarette-smoking profiles of currently smoking control subjects

	Men*	Women*	P
Education, y			
<12	14 (82.3)	11 (100)	
≥12	3 (17.7)	0	.14
Age started smoking, y ± SD	15.1 ± 6.2	31.7 ± 18.8	.01
Cigarettes/day, No. ± SD	15.2 ± 11.4	6.4 ± 5.7	.05
Cigarette size			
Regular	13 (72.2)	6 (50.0)	
King	2 (11.1)	1 (8.3)	
100/120 mm	3 (16.7)	5 (41.7)	.32
Cigarette flavor			
Menthol	6 (33.3)	5 (41.7)	
Non-menthol	12 (66.7)	7 (58.3)	.64
Filtered cigarette			
Filtered	15 (83.3)	12 (100)	
Unfiltered	3 (16.7)	0	.14
No. of times tried to quit			
Current smokers, times ± SD	2.5 ± 1.1	2.5 ± 1.6	.95
Former smokers, times ± SD	11.4 ± 30.5	4.6 ± 1.5	.72
Extent inhaled (includes current and former smokers)			
Did not inhale	2 (5.3)	1 (5.9)	
Only into mouth or throat	15 (39.5)	12 (70.6)	
Deeply into chest	21 (55.3)	4 (23.5)	.08

\*Number of men and women may differ because of missing data. Unless otherwise specified, values = number of individuals (%).

sized or longer cigarettes. Men were more likely to smoke non-menthol and unfiltered cigarettes.

Current and former smokers were characterized by the number of quit attempts and depth of inhalation. The number of quit attempts in current smokers was equal in males and females. Among former smokers, however, men reported over twice the number of quit attempts than women. There were also sex differences in perceived depth of inhalation. Among respondents who did inhale, 71% of the women versus 40% of the men reported inhaling only into the mouth or throat. Women were half as likely as men to inhale deeply into the chest.

We also examined smoking status by years of education and income among our Mexican-American control subjects. Those who completed tenth grade or higher were less likely to be current smokers (12%) than their less educated counterparts (40%; data not shown). Similarly, there was an inverse gradient between income and prevalence of current smoking.

Mutagen sensitivity, as a risk factor for lung cancer, was analyzed in a subset of our study subjects (39 case patients and 59 control subjects) for whom cytogenetic analysis had been completed. The average mutagen sensitivity scores by sex and select smoking variables are shown in Table 4. The mean breaks/cell values for men were 1.25 for case patients, compared with 0.78 for control subjects, and the comparable values for women were 0.93 and 0.90. There were no statistically significant differences in the mutagen-sensitivity score by smoking status, pack-years, number of cigarettes smoked, or duration of cessation within either the case or control groups. However, there were consistently higher values for case patients than for control subjects across each variable evaluated.

Table 4. Mutagen sensitivity status by select variables

Variable	Case patients*		Control subjects*	
	No.	Breaks/cell, mean $\pm$ SD	No.	Breaks/cell, mean $\pm$ SD
Sex				
Male	29	1.25 $\pm$ 0.55	36	0.78 $\pm$ 0.34
Female	10	0.93 $\pm$ 0.30	23	0.90 $\pm$ 0.47
Smoking status				
Never	5	1.06 $\pm$ 0.23	30	0.78 $\pm$ 0.38
Former	20	1.22 $\pm$ 0.53	12	0.86 $\pm$ 0.35
Current	14	1.15 $\pm$ 0.58	17	0.90 $\pm$ 0.46
Pack-years				
<25	7	1.15 $\pm$ 0.20	17	0.95 $\pm$ 0.46
$\geq 25$	27	1.20 $\pm$ 0.59	9	0.89 $\pm$ 0.30
Current smokers: No. of cigarettes smoked per day				
<20	2	1.20 $\pm$ 0.14	10	1.07 $\pm$ 0.48
21-29	8	1.24 $\pm$ 0.67	3	0.80 $\pm$ 0.40
$\geq 30$	4	0.94 $\pm$ 0.55	1	0.60
Former smokers				
Pack-years				
<25	5	1.19 $\pm$ 0.23	9	0.82 $\pm$ 0.37
$\geq 25$	15	1.23 $\pm$ 0.60	3	1.01 $\pm$ 0.33
Duration of cessation, y				
$\geq 11$	8	1.30 $\pm$ 0.60	8	0.97 $\pm$ 0.38
3-10	6	1.15 $\pm$ 0.61	4	0.66 $\pm$ 0.21
$\leq 2$	6	1.18 $\pm$ 0.39	0	

\*Number of case patients and control subjects may differ because of missing data.

Overall, 64.1% of the Mexican-American case patients were considered mutagen sensitive. In comparison, 26.2% of the control subjects were considered mutagen sensitive. Table 5 includes the ORs obtained from univariate and multivariate analyses adjusted for age, sex, and pack-years. The risk associated with mutagen sensitivity was higher among former smokers (OR = 4.5; 95% CI = 0.9-21.9) than among current smokers (OR = 2.6; 95% CI = 0.6-11.1). The OR for never smokers who were mutagen sensitive was not reported, because it was based on only one nonsmoking case patient. Mutagen sensitivity appeared to be implicated in risk, especially in younger patients (OR = 15.0; 95% CI = 1.0-228.9) and in those patients with the lowest exposure to cigarettes (OR = 11.0; 95% CI = 1.1-114.1), compared with an OR of 1.7 (95% CI = 0.4-7.6) for the heaviest smokers. The overall OR for mutagen sensitivity was 2.9 (95% CI = 0.8-9.9). Among histologic subtypes of lung cancer, mutagen sensitivity was associated with an elevated risk in patients with adenocarcinoma (OR = 5.9; 95% CI = 0.8-44.3).

## Discussion

According to the census data for 1990, 9% of the U.S. population was of Hispanic origin, represented mainly by three major groups, Puerto Rican, Cuban, and Mexican (19). These three Hispanic groups are different enough genetically, socioeconomically, and culturally that important information is lost when these groups are combined (6). For this reason, we have focused on Hispanics who have described themselves as Mexican-Americans. Although case identification was not population based, only incident cases from metropolitan hospitals in the Houston and San Antonio areas were included. This procedure reduces any potential bias if genotype is associated with survival. Control subjects were community-based volunteers matched on age, sex, and city of case ascertainment. Although control selection methods were not ideal, this is less of a concern when the major study hypothesis is focused on genetic rather than on lifestyle factors.

Table 5. Univariate and multivariate risk estimates of mutagen sensitivity by smoking status, age, pack-years of exposure, and histologic subtype of lung cancer

	OR (95% CI)
Smoking status	
Former	4.5 (0.9-21.9)
Current	2.6 (0.6-11.1)
Age, y	
<55	15.0 (1.0-228.9)
$\geq 55$	4.2 (1.7-10.7)
Pack-years of exposure	
<25	11.0 (1.1-114.1)
$\geq 25$	1.7 (0.4-7.6)
Histologic subtype of lung cancer*	
Adenocarcinoma	5.9 (0.8-44.3)
Squamous cell	0.8 (0.1-6.9)
Small cell	1.4 (0.1-12.7)
Other	4.3 (0.4-43.3)
All	2.9 (0.8-9.9)

\*Adjusted for age, sex, and pack-years of exposure.



The prevalence of current smoking among the control subjects was 28.6% for the men and 30% for the women. The prevalence for men was exactly the same as that reported in 1985 survey data (28.5%) (5). However, the prevalence for women was substantially higher than that documented by surveys of Hispanic women (17% in 1985 data) (5). A large number of female control subjects will be needed to verify this finding. The inverse association between education and smoking prevalence is well documented (8,9), as is the earlier age of initiation of smoking in Hispanic men compared with Hispanic women.

We also compared the cigarette-smoking data with those derived from the African-American control subjects; these data were collected using the same interview instrument and interviewers (16). There were more nonsmokers among Mexican-American case patients (16.4%) than among African-American case patients (5.7%). A similar pattern was evident for control subjects (48.6% for Mexican-Americans and 38.5% for African-Americans).

However, we also noted that our Mexican-American case patients and control subjects reported more pack-years of exposure (53.5 and 22.7, respectively) than the African-American case patients and control subjects (43.8 and 12.7, respectively) (16). This finding reinforces the importance of studying susceptibility markers in these population subgroups to explain the substantially lower lung cancer rates reported for Hispanics.

The mutagen sensitivity data reported for this small subset of Mexican-American patients accord well with comparable data for African-Americans (16). The prevalence of mutagen sensitivity in case patients was 64.1% for Mexican-Americans and 55.3% for African-Americans. Among control subjects, the prevalence was also remarkably similar, 26.2% for Mexican-Americans versus 24.6% for African-Americans. Mean breaks/cell values for male and female Mexican-American case patients were 1.25 and 0.93, respectively, compared with 1.24 and 1.00, respectively, for African-American male and female case patients. We were also able to confirm our previous findings that neither current smoking status nor years of exposure shifted the sensitivity profile of case patients and control subjects. Our African-American subjects also had higher risks associated with mutagen sensitivity for former smokers than for current smokers and for younger case patients than for older case patients. We also found higher risks associated with mutagen sensitivity for persons in the least exposed smoking stratum. It has been noted that individuals with the susceptible cytochrome P450 1A1 genotype develop lung cancer with lower pack-years of cigarette exposure than do those who have the nonsusceptible genotype (20). The mutagen sensitivity phenotype appears to act in the same fashion. Genetic differences in risk tend to be lower at high dose levels, where environmental influences may overpower genetic predisposition.

We had predicted a priori that one explanation for the lower incidence of lung cancer in Mexican-Americans might be a lower prevalence of mutagen sensitivity. These preliminary data do not support this hypothesis. However, mutagen sensitivity is only one of an array of potential susceptibility markers that may predict cancer risk. In particular, the internal dose of carcinogens in tobacco may be modulated by genetic polymorphisms in the enzymes responsible for activation and detoxification of the

tobacco carcinogens. While considerable attention has been devoted to evaluating the frequencies of polymorphisms in the cytochrome P450 genes and glutathione-S-transferase family of genes in white and African-American populations in the United States, few studies have included sufficient numbers of Hispanic subjects. We are in the process of expanding the study and of genotyping our case patients and control subjects for these polymorphisms in order to evaluate the role of gene-environment interactions in this unique population of case patients and control subjects.

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# Cancer in Hispanics: Issues of Concern

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Hispanics are among the fastest growing minorities in the United States, after Asian-Americans and Pacific-Islanders. Hispanics, Latinos, Chicanos, Mexican-Americans, Puerto Ricans, Cuban-Americans, etc. are all designations used to describe this large, heterogeneous population with different cultural, ethnic, geographic, and social backgrounds. There is still no clear definition of the term "Hispanic." The data available regarding the incidence, morbidity, and mortality from cancer in Hispanics are scarce, scattered, outdated, and often incomplete. From the studies looking at the accessibility and availability of medical care for this population, few have examined in detail the variability within the entire Hispanic population. The aggregation of culturally distinct subgroups, which have resided in the United States for different periods of time, into a more inclusive Hispanic category assumes that all persons of Mexican, Cuban, and Puerto Rican extraction have similar needs and experience similar barriers in using health services. There is, however, no clear evidence for this assumption. On the contrary, there is evidence that each group has specific characteristics that make it different and independent from another, despite the fact that they also share some commonalities. Because of the lower overall prevalence of cancer in this population, potential protective factors need to be explored. Hispanics, however, appear to have a less favorable stage of disease at presentation and have overall lower death rates from cancer than non-Hispanic whites, but lower overall survival in certain cancers. Demographic and epidemiologic data collection need to be updated and improved. Recruitment of minorities, specifically Hispanics, to clinical trials has been a significant problem that can potentially be overcome by adequate protocol development and education of investigators, patients, and health providers regarding specific knowledge, attitudes, and needs of minority populations. [Monogr Natl Cancer Inst 18:35-39, 1995]

Hispanics are a very heterogeneous population, with different cultural, ethnic, geographic, and social backgrounds (1). They are among the fastest growing minorities in the United States, after Asian-Americans and Pacific-Islanders (2,3). Census Bureau predictions indicate that the Hispanic population is growing five times faster than the general population of the United States (4,5). The Hispanic population increased by 61% in the decade between 1970 and 1980 (4). Between 1980 and 1993, there was an increase of 37.6%, from 14.6 to 20.1 million (4). Bureau of the Census figures indicate that by the year 2050,

Hispanics may number over 96 million, accounting for more than 25% of the U.S. population. The difference in the increase between 1970-1980 and 1980-1990 may be somewhat artificial, because there has been an important change in how Hispanics are identified. Until recently, they were included among the Caucasian population, without a precise categorization of Hispanic, Latino, Chicano, Mexican-American, etc.

## Data Collection

The data available regarding the incidence, morbidity, and mortality from cancer in Hispanics within the United States are scarce, incomplete, and often outdated (4-20).

According to a recent report by Villar and Menck (12), some Hispanics have a high concentration of cancer risk factors coupled with well-known barriers against cancer prevention, early detection, access to care, and treatment. They have a higher incidence of certain malignancies (compared with non-Hispanic whites), and although Hispanics overall have a lower total incidence of cancer than non-Hispanic whites, their overall survival rate is lower (12).

Unfortunately, most scientific studies make no distinction among the different groups that comprise Hispanics and thus frequently use the term "Hispanic" to refer to all of the different groups mentioned. Thus, they may extrapolate data from one particular Hispanic subgroup to others where this extrapolation may not always be valid. In this paper, we will refer to each specific Hispanic population when the data available are known. We will use the general term "Hispanic" when specific subpopulation data are not available.

The four major Hispanic subgroups (Mexican-Americans, Cuban-Americans, Puerto Ricans, and the broad category designated as "other") taken together are younger, poorer, and more likely to live in larger, urban dwellings than the U.S. general population (5-11).

Several studies (2,5,6,15,21-25) have looked at access to medical care and barriers encountered by Hispanics and compared them with the population at large. Few have studied

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See "Notes" section following "References."



potential variations within the individual groups of the Hispanic population (2,3,7,15,20,23,26,27). The aggregation of culturally distinct subgroups into a more inclusive Hispanic category assumes that persons of Mexican, Cuban, and Puerto Rican extraction have similar needs and encounter similar barriers in their use of health services. However, this aggregation is not clearly supported in the literature and may itself be a barrier to health care (3,23,25).

## Attitudes Toward Cancer

According to a report by Clark et al. (28), Hispanics are less convinced than Anglo- or African-Americans of the effectiveness of cancer treatment. They believe less in early detection and are less likely to seek preventive health care (22,23). However, they are very concerned about side effects from cancer treatment and are more fatalistic. Forty percent of Hispanics say that someone in their family has or has had cancer (28). They fear cancer more than any other disease, and where 91% of the general population believe they have a fairly good chance of being cured of cancer with early detection, only 74% of Hispanics are convinced that early detection is useful (28). Among Hispanic groups, Cuban-Americans believe the most strongly in the value of early detection, while Mexican-Americans trust this method of preventive care the least (28). Fifty-seven percent of Hispanics believe that eating certain foods may be protective against some kinds of cancer (29). In Hispanic cultures, there is a tendency toward withholding information about cancer from the patient, including prevention, screening, and prognosis (30).

Other problems often faced by Hispanics are health maintenance and discrimination or a perception of discrimination regarding health care, with access to care being a considerable problem in these groups (31). Hispanics overall, especially women, give their own health maintenance a low priority in comparison with that of their children and family (22,28). Clark et al. (28) found that 27% of Hispanics have felt discriminated against concerning the quality of health care they receive, with a 30% overall feeling they are not treated with respect. Twenty-eight percent feel they do not have the same opportunity to obtain health information as do non-Hispanic whites, and 22% feel that they have been discriminated against when seeking health care (28,29).

Language continues to be an important barrier often found in accessing Hispanic populations. The use of interpreters cannot substitute for the ability to speak Spanish (2,32). Because of subtleties in communication and because Hispanics tend to be highly attuned to nonverbal messages, non-Spanish-speaking providers are clearly at a disadvantage in understanding Hispanic patients' needs and in expressing specific recommendations (32). Overcoming language and cultural barriers is essential to the provision of quality health care and continuity of treatment. Pilot studies that have examined interactions and patient satisfaction with physicians and health care providers have shown that those participants who become fluent in Spanish before starting work in a community composed mainly of Hispanic people unanimously report that their ability to communicate without the use of translators has been useful in better

understanding patients' descriptive health status and breaking through cultural barriers (33). They also developed much better relationships with their patients, who were much more trusting and open in their communication than in those cases where a translator was necessary (33).

## Cancer Incidence

Through the Surveillance, Epidemiology, and End Results (SEER)<sup>1</sup> population-based registries, New Mexico, San Francisco, and Puerto Rico have been the only areas that have been able to generate significant data on incidence, morbidity, and mortality from cancer in Hispanics (17,34). None of the other current members of the SEER registry, except Los Angeles, which was added to the registry in 1992, has a large enough Hispanic population to be able to provide sensitive data regarding Hispanics and cancer. Cancer-ethnic data from states such as Arizona, California, Colorado, Florida, and New Jersey are slowly becoming available to some extent through state registries. However, as useful as these data are, they are still quite recent and incomplete. Unfortunately, much of the data from SEER have been retrieved by using surnames, which are often misleading, since they may include non-Hispanics who have adopted a Hispanic surname by marriage; this method fails to include those people who adopt a non-Hispanic surname and their subsequent generations (4).

Cancer incidence, as well as attitudes, varies among Hispanics from different states, even within the same geographic region. Data from the University of Southern California Cancer Surveillance Program and the United States SEER Program show that there are marked differences in cancer rates between Hispanic and non-Hispanic white females in Los Angeles and New Mexico. For example, there is an overall cancer incidence of 38.5 per 100 000 in non-Hispanic whites in Los Angeles compared with 18.7 per 100 000 in Los Angeles Hispanics and 15.1 per 100 000 population in New Mexico Hispanics. Breast cancer has an incidence rate of 105.7 per 100 000 in non-Hispanic whites compared with 62.2 and 52.2 per 100 000 in Los Angeles Hispanics and New Mexico Hispanics, respectively. Similar differences are apparent for colon and rectal cancers. However, the opposite is true for invasive cervical cancer where the incidence rate is 8.1 per 100 000 in non-Hispanic whites in Los Angeles compared with 20.8 in Los Angeles Hispanics and 14.9 in New Mexican Hispanics (9,17).

Several investigators (15,16,20,26) have looked at cancer incidence and mortality within minority population subgroups; however, only a few have addressed the heterogeneity or migratory problems of Hispanics. Several have distinguished Hispanic subpopulations in their use of medical care (3,7). Mexican-Americans are taught to endure sickness as a sign of strength, and they tend to have a stronger sense of privacy than non-Hispanic whites (19). They also rely more heavily on home remedies and care by family members (2,19). Mexican-Americans report fewer health problems than do non-Hispanic whites or African-Americans (19,29,35,36). Generally speaking, Hispanics regard good health as the absence of illness and do not accept the definition of good health as "a state of well being that should be maintained" (2,12,23).



## Cancer: the Problem

Cancer is the second leading cause of death in the United States. The American Cancer Society (ACS) reports that in the United States there were more than 1 100 000 people newly diagnosed with cancer in 1994; more than 540 000 died of the disease, and more than 100 000 deaths could have been prevented through early detection and treatment programs (26,29,33,34). In the last decade, there were over 12 million people under medical care for cancer, almost 9 million new cancer diagnoses, and 4.5 million deaths from cancer (28,34). In terms of ethnicity, the ACS mostly compares data for African-Americans and non-Hispanic whites and states that there is a disproportional cancer rate and mortality among African-Americans (7,29,34). The ACS's report describes "... an underscored urgent need for extensive cancer education and information programs directed to Hispanic-Americans ... who are not adequately aware of most of the warning signals of cancer or of ways to reduce cancer risk" (3,28). The report, as well as the National Health Interview Survey (NHIS) and the HHANES, identifies some specific barriers: cultural, psychologic, and economic. Yet, except for the HHANES, it does not propose any specific solutions or recommendations to overcome these problems. Ramirez and McAlister (37) reported in their 1988 study a "conspicuous absence of health education programs directed at the U.S. Hispanic population."

Hispanics have twice the incidence of cervical cancer as do non-Hispanic whites and are seven times less likely to know the cancer warning signs (20,21,28). New-Mexican Hispanics and other Mexican-Americans living in the west and southwest also have a higher incidence of gastric, pancreatic, gall bladder, and hepatic cancers than non-Hispanic whites (2,8,38). Although they have a lower incidence of certain cancers, such as breast, oral cavity, colon, rectum, and urinary bladder, their mortality from these is similar to that of the general population (2,15,16). SEER data have found that 246.2 per 100 000 Hispanics develop cancer compared with 325.7 per 100 000 for non-Hispanic whites. However, overall cancer mortality is quite similar: 149.8 per 100 000 for Hispanics and 159.8 per 100 000 for non-Hispanic whites (4,19). Hispanics have had difficulty accessing the health care system, which may result in a delay in cancer education, screening, detection, and treatment (2,13,23,39).

Puerto Rican-born residents of New York City have lower colorectal, lung, breast, and ovarian cancer incidence rates than non-Hispanic whites, but twofold higher rates of gastric cancer and threefold higher rates of esophageal and cervical cancers (6,16,20,24). The mortality rate for esophageal cancer is almost twice as high for male, Puerto Rican-born residents of New York City than non-Hispanic white males. The gastric cancer mortality rate is approximately 20% higher for both male and female Puerto Rican-born New Yorkers (16,20,24).

Hispanics have a lower incidence of cancer in the lower intestinal tract. This may reflect, at least in part, dietary protective factors, such as the high consumption of beans, rice, corn (tortillas), and other grains, which are staples of the Hispanic diet (2,11,23). The lower incidence of breast cancer may reflect other protective factors, such as early pregnancy, multiparity,

and less use of oral contraceptives and other hormonal agents (2,11). Breast cancer, however, has increased three times faster in Hispanic women than in non-Hispanic whites (2,8,13,34). The role of diet, amount of fat intake, and obesity in Hispanics in cancer prevention is currently being evaluated (2,36,40,46).

Since the majority of mainland U.S. Hispanics are Mexican-Americans (60%) and because of the lack of available health data concerning this group, we have attempted to obtain cancer incidence information on new arrivals and unacculturated Mexican-Americans (4,19,41). In this regard, it is worthwhile to study the National Cancer Registry from Mexico City, a population-based registry, where the following cancers represented more than 50% of the total number of new cancer diagnoses in 1987: cervix (19.8%), breast (11.1%), lymphoma (5.1%), prostate (4.4%), stomach (4.1%), leukemia (3.9%), and lung (3.0%). It is important to point out that in this registry, more than 60% of all cancer cases were in females; however, this phenomenon is seen only in subjects over the age of 25 years (42). In females, cervical cancer is the leading cancer in incidence and mortality (42). In Mexico, approximately 15%-20% of new cervical cancer diagnoses are adenocarcinoma or adenosquamous cancers compared with a 5% worldwide occurrence of these histologies (42). In the United States, according to the ACS, cervical cancer kills more than 7000 women each year (34). Cervical cancer occurs in 24 per 100 000 women in Puerto Rico, but in 1989 only 45% were invasive, a figure that has decreased from 92.1% in 1950 (14,27). HHANES and other studies have shown that a significantly higher percentage of Hispanics compared with non-Hispanic whites and African-Americans had either never had or heard of a Pap smear (22,25). Others (12) have also shown that Hispanics have more advanced cervical cancer, which either goes untreated, or if treated, is likely to receive surgery alone. Similar differences exist between the three ethnic groups regarding breast examinations and mammography (22,25). There is less early-stage breast cancer in the Hispanic population, and there are considerable treatment differences between Hispanics and non-Hispanic whites in this area (12).

## Recruitment to Clinical Trials

The National Cancer Institute (NCI) has placed a priority on the problems related to recruitment of minority populations to clinical trials. Recruitment of all minorities to clinical trials is significantly lower than recruitment of non-Hispanic whites (43-48). In our recently concluded study at the Arizona Cancer Center and in ongoing community recruitment trials, we found that through community education, involving both the medical and lay communities regarding the facts about clinical trials, dispelling the fear about being used as guinea pigs, developing protocols specific to the needs of Hispanics, and providing the community with Spanish-speaking consent forms and providers, recruitment of Hispanics into clinical trials, both in Southwest Oncology Group (SWOG) studies and "in-house" studies at the Arizona Cancer Center, reached over 40% of the overall population and 22% of new patients seen at Arizona Cancer Center between 1990 and 1992. Currently, early and preliminary findings from a follow-up of the same approach being conducted by a community-based cancer center (Cancer Care Center of



Southern Arizona) show no difference in recruitment of minorities versus nonminority populations into clinical trials (43-48).

The most important reasons why minorities have not been accrued into clinical trials at the same rate as nonminorities can be summarized as follows: 1) different cancer incidence in minorities than in whites, with lack of protocols that address cancers seen most often in minorities; 2) lack of understanding of minorities' knowledge, attitudes, and practices regarding cancer and cancer treatment, resulting in poor protocol planning; 3) fear of being used as guinea pigs still prevalent in both the medical and lay communities; 4) lack of awareness of existing protocols by physicians and by the lay community; 5) treatment protocols often not available at patients' preferred or designated cancer treatment site (Health Maintenance Organizations, Preferred Provider Organizations, solo or group practices with no affiliation to clinical research groups, rural sites, etc.); 6) financial constraints and strict requirement of costly and often clinically irrelevant studies and procedures at specific times during course of treatment; 7) high frequency of office visits required that put an additional burden on patients who often cannot afford any more time away from work, family, or home or who have transportation difficulties, making it impossible for them to become eligible to participate in state-of-the-art clinical trials; 8) length of time it takes for physicians and staff to translate and explain protocols and consent forms; and 9) strong deficiency of Spanish-proficient providers and staff that can not only translate treatment plan, protocols, and consent forms but also develop the rapport needed to treat cancer patients.

To adequately recruit minorities into clinical trials, one must necessarily include academic centers, but perhaps most important, one must also recruit the medical community to participate. Community recruitment and involvement will increase representation of women and minorities in all trials as subjects and as investigators, will accrue subjects much more rapidly into certain trials, might increase the commitment of sponsoring institutions and investigators to the community, and because of the lack of academic overhead, may decrease the cost of clinical research by as much as 50%.

## Conclusions

Unfortunately, there are no complete data regarding cancer in all Hispanic groups. We currently do not know the true number of cancer cases in Hispanics, nor do we have accurate morbidity, mortality, and survival data from these groups. As a result, we are not really able to fully understand or appreciate the physical, emotional, and financial impact of cancer in Hispanic patients and their families.

Mortality from cancer in Hispanics is difficult to assess because of the limited data that are available (17,21). It is difficult to rely solely on the SEER program, since it reflects primarily data from New Mexican and Puerto Rican Hispanics and these may not accurately reflect the overall picture of the U.S. Hispanic population. This has been addressed and will change with the additional centers that have been recruited to the SEER program, particularly the Los Angeles area. Cancer registries and databases that include needs and problems of specific

minority populations, according to ethnic background, geographic location, time of U.S. residence, etc., are expensive and often cumbersome. However, until we can truly understand the needs of each of the different Hispanic subgroups, these types of registries may be the only means by which such information can be collected. These registries could have a role not only in descriptive epidemiology, but also in cancer control efforts designed to meet the needs of each community. They should serve as tools for evaluation of direct (incidence, survival, and mortality) and indirect (risk factors, screening, early detection, knowledge, attitudes, and practices) measures of cancer.

It is important that new population-sensitive programs and interventions that involve the Hispanic communities be developed. These programs should focus on issues such as diet, education, smoking, and general cancer awareness and should emphasize potential protective factors within each population, rather than focusing only on problems of the disadvantaged and underserved.

The need to continue to focus on making state-of-the-art cancer treatment, including clinical trials, available to all minority populations cannot be emphasized enough. Efforts at recruitment into clinical trials must deal with cultural and community issues. Clinical trials for the type of neoplasms seen in these populations, even if rare in nonminorities, should be encouraged. Using existing community groups and organizations to help create strong community bonds could improve the potential for success of minority cancer control efforts and patient recruitment to clinical trials. These programs can become trusted networks of information for their respective communities. In developing these interventions, we should increase our awareness of the needs of all different Hispanic groups and ensure that programs are developed together with these communities so that they are culturally and community sensitive, respecting and complementing the Hispanic heritage.

The time has come to revise and update our sources of information and data gathering. Careful study of each Hispanic subgroup is essential to have a realistic picture of the overall cancer problem in the United States today. These studies must include a clearer definition of the differences among the many Hispanic subgroups with their respective problems and barriers to cancer care. We cannot achieve the desired cancer goals for the year 2000 of reducing cancer mortality by 50% and increasing the number of people cured without accurate, sensitive, and up-to-date data on each population group. We should learn from programs, such as the NHIS, the HHANES, and the North American Conference on Cancer in Hispanics; however, by no means do these programs complete our task.

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## Notes

<sup>1</sup>*Editor's note:* SEER is a set of geographically defined, population-based central tumor registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Each registry annually submits its cases to the NCI on a computer tape. These computer tapes are then edited by the NCI and made available for analysis.

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# Comparing Acculturation Scales and Their Relationship to Cancer Screening Among Older Mexican-American Women

Lucina Suarez, LeaVonne Pulley\*

**Background:** Hispanic women in the United States are less likely to participate in breast and cervical cancer screening than women of other racial and ethnic groups. To plan appropriate interventions requires an understanding of the barriers to participation, including those of acculturation and assimilation. Few studies have examined the effects of acculturation and assimilation on the cancer-screening behavior of Mexican-American women. **Purpose:** Because of the extensive use of the Cuellar acculturation scale and the more recent use of the Hazuda scale, we explore the utility of these two measures to predict Pap smear and mammography screening. Using a population-based sample of Mexican-American women aged 40 years and older, we compare the two scales with each other and describe their relationship to sociodemographic factors and to participation in cancer screening. **Methods:** The data are from baseline surveys in El Paso and Houston, Tex., conducted before the implementation of community interventions to improve Pap smear and mammography screening in low-income Mexican-American women. Study subjects were 923 randomly selected Mexican-American women aged 40 years and older living in 16 El Paso census tracts and seven Houston census tracts. Personal interviews solicited information on age, marital and employment status, household annual income and size, education, health insurance coverage, Pap smear and mammogram history, and a series of acculturation dimensions. Acculturation was measured using the abbreviated version of the Cuellar scale developed for the Hispanic Health and Nutrition Examination Survey, 1982-1984, and the Hazuda scale developed for the San Antonio Heart Study. The eight-item Cuellar acculturation scale assessed the extent to which Spanish and English were spoken, preferred, read, and written; the ethnic identification of the respondent and her parents; and generational status in the United States. The Hazuda scale assessed the following dimensions of acculturation: adult proficiency in English, adult pattern of English versus Spanish language usage, value placed on preserving Mexican cultural origin, attitude toward traditional family structure and sex-role organization, and adult interaction with members of mainstream society. **Results:** The Cuellar scale was highly correlated with Hazuda's two language dimension. The Hazuda scale dimensions, Mexican cultural values and traditional family attitudes, correlated the least with Cuellar's scale. All the ac-

culturation dimensions, Cuellar's and Hazuda's, were strongly associated with education and health insurance coverage. With the use of multiple logistic regression to adjust for education, health insurance, and other variables, English proficiency was a predictor of both a recent Pap smear and a recent mammogram. No other language-based acculturation dimension was associated with a recent screening with adjustment for education, health insurance, and other variables. However, in controlling for these factors, we found that a woman's attitude toward traditional family structure was related inversely to mammogram screening. That is, women who held the strongest traditional Mexican family attitudes were more likely to participate in mammography screening. **Conclusion:** This study shows the importance of separating the effects of acculturation on cancer screening from those due to social and economic conditions. Results suggest that the Hazuda scale provides a more multidimensional approach than the Cuellar scale and is a superior measure of the acculturation process. Traditional Mexican family attitudes positively influence mammogram-screening behavior, and this finding has implications for cancer control interventions in this population. [Monogr Natl Cancer Inst 18:41-47, 1995]

Hispanic women in the United States are less likely to participate in breast and cervical cancer screening than are women of other racial and ethnic groups (1,2). To understand why this is true and to plan appropriate environmental, social, organizational, and individual interventions requires an understanding of the barriers to participation. Access to care is a serious issue, since Hispanics often lack health insurance (3); however, acculturation and assimilation barriers also require examination.

For Hispanics, acculturation is the adoption of attitudes, values, and behaviors (including language ability) of the dominant non-Hispanic white culture. Assimilation is the integration into the other culture, interacting with non-Hispanic whites as

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See "Note" section following "References."



friends, neighbors, and co-workers. These terms are sometimes used interchangeably and often inconsistently. Nonetheless, various acculturation and assimilation indicators have been used to try to understand the health behavior of Hispanics in the United States (4-8). A review of studies examining the effects of acculturation on cigarette smoking, alcohol consumption, and use of health- and cancer-screening services shows inconsistent results (5-20). Some research (4,8,9,12,14,18,20) suggests that highly acculturated Hispanics are similar in knowledge and risk behavior to non-Hispanic whites. Other studies (6,7,10,11,19) found little or no effect of acculturation. Interpreting these findings is difficult, given the varied measures used and health behaviors studied and the failure to address the confounding effect of sociodemographic factors.

Only three studies (19-21) have examined the effects of acculturation on Pap smear and mammography screening with consideration of socioeconomic factors. In a study of older Hispanic women living in public housing in Los Angeles, Calif., Marks et al. (19) reported small effects of language preference on lifetime prevalence of Pap smear and recency of mammography. Using a four-factor assimilation scale and controlling for age and education, the authors concluded that access to services and sociodemographic factors were stronger determinants of Hispanic health behaviors than was assimilation. Elder et al. (20) in a San Diego, Calif., telephone survey of cancer-related behaviors combined five factors into a single measure of acculturation: 1) language-reading preference, 2) language-speaking preference, 3) country of childhood/adolescence, 4) ethnicity of friends, and 5) pride in Latino heritage. Controlling for age, education, marital status, and income, Elder et al. found trends in Pap smear and mammography use favoring Anglo women, followed by highly acculturated, and then less acculturated women. In a population-based study of Mexican-American women aged 40 and older in El Paso, Tex., adjusting for age, education, income, and health insurance status, only one of five acculturation dimensions predicted screening behavior (21). Women who were less acculturated regarding traditional family structures and sex-role orientation were more likely to have had a recent mammogram.

Both Marks et al. and Elder et al. assessed acculturation status by using items from a popular acculturation scale developed by Cuellar, Harris, and Jasso in 1980 (22). The third study measured acculturation status with a scale developed by Hazuda, Stern, and Haffner in 1988 (23). Both Cuellar and Hazuda developed their scales specifically for Mexican-American populations. The original Cuellar scale and various adaptations have been widely used in health and mental health research. The Hazuda scale initially developed for the San Antonio Heart Study has recently been adopted by many investigators in cancer control research (Ruiz E: personal communication).

A discussion of the complex debate over all the models and measures of acculturation and assimilation is beyond the scope of this article. Because of the extensive use of the Cuellar acculturation scale and the more recent use of the Hazuda scale, we wanted to explore the utility of these two measures in predicting cancer screening. Using a population-based sample of Mexican-American women aged 40 years and older, we compare an abbreviated version of the Cuellar scale with the Hazuda scale. We

compare the two scales with each other and describe their relationship to sociodemographic factors and to participation in cancer screening. Finally, we examine the independent effect of each acculturation dimension on screening behavior by controlling for sociodemographic variables.

## Methods

### Background

The data are from base-line surveys conducted before the implementation of community interventions designed to increase cancer screening. This study, funded by the National Cancer Institute, is testing an intervention to improve Pap smear and mammography screening in low-income Mexican-American women aged 40 and older living in El Paso, Tex. Mexican-American women aged 40 and older living in Houston, Tex., are the comparison community. The 3-year intervention in El Paso includes quarterly campaigns, featuring peer role models in the media and volunteer activities in the community. Late in 1991 and early in 1992, we conducted base-line surveys of knowledge, attitudes, and cancer-screening practices in 16 El Paso census tracts and in seven Houston census tracts. These census tracts were selected because they were representative of our target population of low-income Mexican-Americans. Populations within these census tracts were 75%-99% Hispanic and had median incomes at or below the federal poverty threshold.

### Study Subjects

Sample selection in El Paso was a simple random sample of all households in the survey census tracts enumerated using the Polk City Directory and the 1990 Census Tract City of El Paso Street Code Reference Manual. The procedure in Houston was multistage; blocks were randomly selected and, from these, every third household was included in the sample. A complete enumeration of sampled households identified all household members by age and sex. Eligible respondents were females aged 40 years and older and Mexican-American by self-report. Only one eligible subject from each household, chosen by recency of birthday, was interviewed. Interviews required written, informed consent from each woman. The Texas Department of Health legal review board approved the El Paso study procedures to protect human subjects, and The University of Texas Health Science Center review board approved the Houston study procedures. Nine hundred twenty-three women (450 women in El Paso and 473 in Houston) completed personal interviews. The response rate was 82% in El Paso and 85% in Houston.

### Study Variables

Using a standard Spanish or English instrument, bilingual Hispanic females conducted 1-hour interviews in the respondent's home. After determining the respondent's language preference, interviewers asked women their age, marital and employment status, household annual income and size, education, health insurance coverage, Pap smear and mammogram history, and a series of questions related to acculturation. Cancer-screening history was ascertained by asking women if they had ever had a Pap smear or mammogram and, if so, the dates of their most recent Pap smear or mammogram. Women were categorized by whether or not they reported a Pap smear or mammogram in the previous 2 years. Pap smears and mammography done because of a health problem were defined as diagnostic examinations, and women reporting such diagnostic procedures were excluded. Thus, the outcome of interest was the use of screening Pap smears or screening mammography as routine prevention services in the absence of symptoms.

Acculturation was measured using two previously published scales developed by Cuellar et al. (22) and Hazuda et al. (23). Both scales were developed and validated in a Mexican origin population. We used an abbreviated version of the original Cuellar 20-item scale developed for the Hispanic Health and Nutrition Examination Survey (HHANES), 1982-1984 (24). This eight-item acculturation scale assessed the extent to which Spanish and/or English was spoken, preferred, read, and written; the ethnic identification of the respondent and her parents; and generational status in the United States. Each item is scaled from 1, representing the least acculturated category, to 5, representing the most acculturated category. As in studies using HHANES data, we created a composite Cuellar index by



averaging scores on all eight items. We used cut points that divided the index into five equidistant categories and labeled them as Cuellar did: very Mexican (1), Mexican-oriented bicultural (2), bicultural (3), Anglo-oriented bicultural (4), and very Anglicized (5). Studies using the abbreviated Cuellar scale have varied in their methods for creating different dimensions from the eight-item scale (6,25,26). Following the lead of Solis et al. (6), we also created three dimensions: 1) language (spoken, preferred, read, and written), 2) ethnic identification (self and parents), and 3) generation. For each dimension, we averaged scores across relevant items and created five equidistant categories reflecting the five Cuellar acculturation types noted above. For language, women in the least acculturated category spoke, preferred, read, and wrote only Spanish. For ethnic identification, location in the lowest acculturation category represented women who described themselves and their parents as Mexican. For the item "generation," the numbers represent the first (born in Mexico) to fifth generation in the United States.

The Hazuda scale assesses five acculturation dimensions: 1) adult proficiency in English, 2) adult pattern of English versus Spanish language usage, 3) value placed on preserving Mexican cultural origin, 4) attitude toward traditional family structure and sex-role organization, and 5) adult interaction with members of mainstream society. The scale has construct validity and provides separate measures of acculturation (23).

Women were assigned a summary score on each dimension by adding response scores of the relevant items. Within each dimension, we grouped women into four categories, rank ordered from least to most acculturated on the basis of previously defined cut points from the San Antonio Heart Study (Hazuda HP: unpublished data). Location in the higher numbered categories represented acculturation toward non-Hispanic white culture. For example, women in the highest English proficiency category were highly proficient in understanding, speaking, and writing English. Women in the highest English usage category interacted with family, friends, neighbors, and co-workers in English, and they listened to, watched, and read English media. For value placed on preserving Mexican cultural origin, women in the highest category felt it was not important for children to know the history of Mexico, follow Mexican customs, or celebrate Mexican holidays. For attitude toward traditional family structure and sex-role organization, women in the highest category felt it was not important that family members know their family tree, have close ties to extended family, remember deceased family members, have married children live close to parents, or concede authority to father or brothers. Women in the highest category for mainstream social interaction had mostly non-Hispanic white friends, neighbors, and co-workers.

Following Hazuda's method, we also combined English proficiency, English use, and social interaction into a composite index that measured adult functional integration with mainstream society. To form the composite index, we converted each dimension's summary score to *z* scores, added them, and used quartiles for categories.

## Analyses

Pearson correlation coefficients were calculated to examine the degree of association between Cuellar and Hazuda acculturation scales. Statistical tests for differences or trends in proportions across various levels of sociodemographic factors or acculturation dimensions were chi-square tests. Using multiple logistic regression, we computed odds ratios (ORs) of having a recent screening Pap smear or mammogram for each gain in acculturation level (27). ORs and 95% confidence intervals (CIs) were computed using the software STATISTIX (28).

For each acculturation dimension and composite index, we present unadjusted ORs with CIs and ORs with CIs adjusted for relevant sociodemographic factors. Variables in the logistic model were coded as follows: age (1 = 40-49 years old, 2 = 50-59 years old, 3 = 60-69 years old, and 4 = ≥70 years old), education (0 = 6th grade or less, 1 = 7th to 11th grade, and 2 = 12th grade or higher), marital status coded as two dummy variables (married, formerly married, or never married), health insurance as two dummy variables (none, Medicaid/Medicare, or private), Cuellar acculturation dimensions and index (1 = very Mexican; 2, 3, 4, 5 = very Anglicized), and Hazuda acculturation dimensions and index (1 = least acculturated; 2, 3, 4 = most acculturated). In preliminary analysis, employment status was not a significant predictor of screening and was excluded from further study. We also excluded household income from the analysis because 25% of study subjects did not know their annual income and only 6% had incomes above 200% of the federal poverty level.

## Results

Seventy-five percent of the women in the study were interviewed in Spanish, and 61% were born in Mexico. Only 16% of the women had graduated from high school, and 49% had no health insurance. Sixty-two percent of the women were married, and only 22% worked outside the home. Eighteen percent had never had a Pap smear, and 65% had never had a mammogram. Sociodemographic characteristics and screening levels of women surveyed in El Paso closely matched those of the women surveyed in Houston.

As shown in Table 1, most women in the study had low acculturation levels on all dimensions. That is, most women used Spanish, identified themselves as being very Mexican, were first generation, mainly interacted with Mexican-Americans, and held strong Mexican cultural and family attitudes. Of all dimensions measured, women tended to be most acculturated on English proficiency (27.9%). Fewer than 1% of women were highly acculturated on ethnic identity, attitude toward traditional family structure and sex-role organization, and interaction with members of mainstream society.

As shown in Table 2, the Cuellar language dimension was highly correlated with Hazuda's English proficiency and use dimensions (.79 and .83), as were ethnic identity (.44 and .52) and generation (.50 and .56). The Cuellar index, a composite of the three dimensions, had nearly identical correlations with Hazuda's dimensions as the single Cuellar dimension of language (e.g., .75 and .79). This was also true for Hazuda's functional integration measure, a composite of the language and social interaction dimensions; correlations with Cuellar's dimensions mirrored those of the single Hazuda dimensions of English proficiency and use (e.g., .73 versus .79 or .83). This finding suggests that the Cuellar index and the Hazuda function-

**Table 1.** Percentage distribution of Mexican-American women aged 40 years or older by acculturation level, El Paso-Houston, Tex., 1991-1992

	Cuellar acculturation scale				
	1	2	3	4	5
	Very Mexican	Mexican bicultural	Bicultural	Anglo bicultural	Very Anglicized
Language	52.7	15.1	16.7	11.4	4.1
Ethnic identity	69.3	9.6	13.6	6.6	0.9
Generation	61.0	27.8	2.3	3.7	5.2
Cuellar index	57.6	17.7	17.5	6.6	0.5

	Hazuda acculturation scale			
	1	2	3	4
	Least acculturated			Most acculturated
English proficiency	39.1	16.4	16.6	27.9
English versus Spanish use	61.3	17.8	17.3	3.6
Value placed on culture	42.2	31.8	18.0	7.9
Traditional family attitude	26.9	45.2	27.2	0.8
Interaction with mainstream society	58.3	27.7	13.2	0.8
Functional integration	23.5	26.5	25.1	24.9

**Table 2.** Correlation\* between Cuellar and Hazuda acculturation scales among Mexican-American women aged 40 years or older, El Paso-Houston, Tex., 1991-1992

Hazuda scale	Cuellar scale			
	Language	Ethnic identity	Generation	Cuellar index
English proficiency	.79	.44	.50	.75
English versus Spanish use	.83	.52	.56	.81
Value placed on culture	.16	.12	.12	.17
Traditional family attitude	.16	.10	.10	.15
Interaction with mainstream society	.37	.28	.29	.40
Functional integration	.73	.47	.48	.72

\*Pearson's correlation coefficient. All correlations differed from zero at  $P < .005$ .

al integration measure are largely a function of language. The two Hazuda measures, Mexican cultural values and traditional family attitudes, correlated the least with Cuellar's measures, with values ranging from .10 to .17.

Table 3 shows how acculturation levels vary with sociodemographic characteristics. Younger women tended to be first generation (born in Mexico) and to value preserving their Mexican cultural origins. Women without health insurance or who had only Medicaid or Medicare were the least acculturated on all dimensions. Acculturation levels also were strongly associated with education level. Those with the least education were the least acculturated on all dimensions. Married women were more often Spanish language users and born in Mexico and seldom interacted with non-Hispanic whites.

Cervical cancer- and breast cancer-screening participation was low; 48% of women had had a Pap smear within the past 2 years, and only 23% had had a mammogram within the past 2 years. Older women, women on Medicare or Medicaid, women with fewer than 7 years of education, and women who had never married were least likely to report a recent Pap smear (Table 4). Women with no health insurance and with the least education were the least likely to have had a recent mammogram (Table 4).

Because acculturation was associated with socioeconomic characteristics, the independent effect of each acculturation dimension was assessed by adjusting for sociodemographic factors with multiple logistic modeling. Tables 5 and 6 show unadjusted and adjusted ORs and their 95% CIs of screening for each level gain in acculturation. After adjustment for age, health insurance, education, and marital status, only English proficiency had an OR indicating a statistically significant association with recent Pap smear screening (OR = 1.18; 95% CI = 1.03-1.35). With adjustment, ORs of having a recent Pap smear for all other language-based dimensions were reduced to nonsignificant levels (Table 5). With mammography (Table 6), the English proficiency dimension had an OR of comparable magnitude (OR = 1.17; 95% CI = 1.00-1.37) but was of borderline statistical significance ( $P = .057$ ). As with Pap smear screening, no other language-based acculturation dimension was associated with a recent mammogram after adjustment for education, health insurance, age, and marital status. However, independent of these factors, a woman's attitude toward traditional family

**Table 3.** Acculturation scales and sociodemographic factors among Mexican-American women aged 40 years or older, El Paso-Houston, Tex., 1991-1992

	Age group, y				Trend test*
	40-49	50-59	60-69	≥70	
Cuellar scale					
% very Mexican language	57.5	48.2	54.0	48.1	.14
% very Mexican identity	65.7	68.1	73.5	72.5	.05
% first generation	70.6	64.2	47.9	56.5	.00000
Hazuda scale					
% low English proficiency	36.2	40.6	37.5	45.8	.15
% low English use	63.0	57.4	60.1	67.5	.64
% strong Mexican culture	48.8	42.5	39.1	32.0	.0007
% strong traditional family attitude	27.2	24.6	26.2	31.8	.47
% low interaction with mainstream society	59.2	58.2	56.7	59.4	.82
Health insurance					
	None	Medicaid/ Medicare	Private	Difference test†	
Cuellar scale					
% very Mexican language	60.3	54.7	36.3	.00000	
% very Mexican identity	72.1	71.9	61.6	.01	
% first generation	71.7	54.7	46.8	.00000	
Hazuda scale					
% low English proficiency	45.9	45.0	20.7	.00000	
% low English use	69.4	67.3	40.0	.00000	
% strong Mexican culture	47.5	37.2	37.0	.006	
% strong traditional family attitude	29.0	26.8	22.9	.23	
% low interaction with mainstream society	65.9	58.8	43.5	.00000	
Education, y					
	<7	7-11	≥12	Trend test*	
Cuellar scale					
% very Mexican language	70.8	23.2	23.6	.00000	
% very Mexican identity	82.9	50.0	42.9	.00000	
% first generation	75.4	37.4	37.8	.00000	
Hazuda scale					
% low English proficiency	57.7	7.9	10.8	.00000	
% low English use	80.6	31.5	29.3	.00000	
% strong Mexican culture	46.2	39.0	34.5	.005	
% strong traditional family attitude	30.1	22.8	19.6	.004	
% low interaction with mainstream society	67.2	45.3	42.2	.00000	
Marital status					
	Married	Formerly married	Never married	Difference test†	
Cuellar scale					
% very Mexican language	57.1	45.9	42.5	.003	
% very Mexican identity	71.9	65.6	62.5	.10	
% first generation	64.3	55.0	60.0	.03	
Hazuda scale					
% low English proficiency	40.8	36.1	40.0	.39	
% low English use	64.1	55.1	67.5	.02	
% strong Mexican culture	42.7	41.4	41.7	.94	
% strong traditional family attitude	27.1	25.9	28.2	.91	
% low interaction with mainstream society	61.8	52.3	55.0	.02	



**Table 4.** Prevalence of screening by sociodemographic characteristics

Characteristic	Pap smear within 2 y, %	Mammogram within 2 y, %
Age, y	*	*
40-49	56.0	19.2
50-59	46.5	27.8
60-69	46.4	22.4
≥70	35.7	22.0
Health insurance	*	*
None	48.7	16.6
Medicare/Medicaid	38.1	20.4
Private	56.2	36.7
Education, y	*	*
<7	42.1	19.5
7-11	55.4	27.1
≥12	60.1	29.5
Marital status	*	*
Married	51.6	25.0
Formerly married	43.9	20.1
Never married	23.7	10.8

\*Significant differences in prevalences between categories of each sociodemographic factor at  $P < .05$ .

**Table 5.** ORs and 95% CIs of having a screening Pap smear for each level gain in acculturation

	OR (95% CI)	Adjusted* OR (95% CI)
Cuellar acculturation scale		
Language	1.19† (1.06-1.33)	1.08 (0.95-1.24)
Ethnic identity	1.02 (0.89-1.17)	0.90 (0.78-1.05)
Generation	1.08 (0.95-1.23)	1.01 (0.88-1.17)
Cuellar index	1.19‡ (1.03-1.36)	1.04 (0.88-1.23)
Hazuda acculturation scale		
English proficiency	1.27† (1.13-1.41)	1.18‡ (1.03-1.35)
English versus Spanish use	1.31† (1.12-1.53)	1.16 (0.96-1.40)
Value placed on culture	0.89 (0.77-1.03)	0.88 (0.76-1.02)
Traditional family attitude	0.93 (0.78-1.12)	0.87 (0.72-1.05)
Interaction with mainstream society	1.11 (0.92-1.33)	1.06 (0.87-1.29)
Functional integration	1.19† (1.05-1.34)	1.06 (0.91-1.23)

\*Adjusted for age, health insurance, education, and marital status.

† $P \leq .01$ .

‡ $P \leq .05$ .

**Table 6.** ORs and 95% CIs of having a screening mammogram for each level gain in acculturation

	OR (95% CI)	Adjusted* OR (95% CI)
Cuellar acculturation scale		
Language	1.24† (1.09-1.40)	1.11 (0.95-1.29)
Ethnic identity	1.14 (0.98-1.32)	1.06 (0.90-1.26)
Generation	1.17‡ (1.02-1.34)	1.09 (0.93-1.28)
Cuellar index	1.29† (1.11-1.50)	1.14 (0.95-1.37)
Hazuda acculturation scale		
English proficiency	1.30† (1.14-1.47)	1.17 (1.00-1.37)
English versus Spanish use	1.38† (1.16-1.63)	1.17 (0.95-1.45)
Value placed on culture	1.09 (0.92-1.29)	1.03 (0.87-1.23)
Traditional family attitude	0.83 (0.67-1.02)	0.75† (0.60-0.94)
Interaction with mainstream society	1.19 (0.97-1.47)	1.04 (0.83-1.30)
Functional integration	1.34† (1.16-1.55)	1.17 (0.98-1.39)

\*Adjusted for age, health insurance, education, and marital status.

† $P \leq .01$ .

‡ $P \leq .05$ .

structure was inversely related to mammogram screening (OR = 0.75; 95% CI = 0.60-0.94). That is, women who held the strongest traditional Mexican family attitudes (importance of extended family and male primacy) were more likely to participate in mammography screening.

## Discussion

This study shows the importance of separating the effects of acculturation on cancer screening from those due to social and economic conditions. All the acculturation dimensions that we examined were strongly related to education and health insurance status. Consequently, most of the acculturation dimensions, especially those based on language, have no independent association with recent screening. Many past studies of cancer screening and smoking behavior have relied on language use alone as a surrogate measure for the complex process of acculturation (2,29-31). Unfortunately, these "acculturation" studies may have simply measured the strong effects of education and socioeconomic status on health behavior (14,32). We believe that it is still important to measure acculturation in cancer-screening behavior research, particularly because of our significant finding on family attitudes. But others have noted, and we concur, that any examination of acculturation should control for socioeconomic status and education (14,33,34).

The principal results of our study come from the direct comparison of two well-documented acculturation scales. We followed the lead of Solis et al. (6) in separating the abbreviated Cuellar index into three dimensions, but it is not clear that these dimensions measure distinct constructs. The two Hazuda language dimensions correlated highly and identically with the Cuellar language dimension and the overall Cuellar index. The scale items for ethnic identity and generation, both poor predictors of screening, contributed essentially no information toward the Cuellar index. This implies that the abbreviated Cuellar index developed for HHANES is language driven and that the Hazuda language measures provide comparable data. The other three Hazuda dimensions (value placed on culture, traditional family attitude, and interaction with mainstream society) correlated weakly with the Cuellar dimensions and index. This finding suggests that the Hazuda scale provides more acculturation information separate from language use, and, in fact, this characteristic is one of its primary qualities (23). Furthermore, all of the Cuellar measures grouped at least 50% of study subjects into the lowest acculturation category, while only two of Hazuda's measures had this effect. These observations indicate that Hazuda's multidimensional scale is a superior measure of the complex pattern of acculturation in Mexican-Americans. However, these results may not be true for other Hispanic groups (e.g., Central Americans and Puerto Ricans). In addition, because our study population included women living in census tracts with high concentrations of Mexican-Americans, it is likely that highly acculturated individuals were excluded, further limiting our conclusions.

By examining the independent relationship of each acculturation dimension to Pap smear and mammography screening, we identified two significant predictors: English proficiency and traditional Mexican family attitudes. The other dimensions, eth-



nic identity, generation in the United States, Mexican cultural values, and interaction with mainstream society, were poor predictors of cancer screening. This result is consistent with that of other studies that have failed to find any association between ethnic identification, birthplace, or generation with recency of screening or use of preventive health services (2,6,19). Previous findings from the El Paso study also showed no effect on screening from acculturation dimensions measuring Mexican cultural values or interaction with mainstream society (21).

In contrast to Cuellar's language "preference" measure, Hazuda's measure of English proficiency was an important determinant of Pap smear and mammography screening. The distinction between being proficient in English and preferring to speak Spanish may be important, particularly in Hispanic communities where Spanish language is pervasive. As suggested by Solis et al. (6) and our study, it is the inability to speak English, rather than a Spanish language preference, that is a barrier to using preventive health services. English language proficiency may be less of an issue in communities where Spanish-speaking providers are readily available. To avoid confounding the effects of acculturation and access, we recommend that studies of cancer-screening behavior not use a respondent's language preference in an interview as a measure of acculturation status.

Adjustments for sociodemographic factors revealed that low acculturation on traditional Mexican family attitudes positively influences mammogram screening. This finding has been reported previously from the El Paso study (21). It is not clear why this acculturation dimension did not also influence Pap smear screening, although results showed that the ORs were in a similar positive direction. The lack of a significant effect on Pap smear screening may be due to the much higher prevalence of the Pap smear and the relative newness of the mammogram in this population.

In this study, family attitude was the one dimension that varied least with language use, ethnic identity, or generation. The family attitude scale has four items related to family ties and the extended family and three items related to sex roles or the dominance of males in the family. Sabogal et al. (35) suggested that this Hispanic core value of familism is strongly maintained even with changes in language or the ethnic identity assimilation process. Traditional family attitudes might influence screening behavior in a variety of ways. Family attitudes may be a surrogate measure for a social and family support network that influences health behavior by providing emotional, informational, or more tangible economic support. Our finding of the importance of family in mammogram-screening behavior of Mexican-American women has implications for interventions. In our intervention community (El Paso, Tex.), we have incorporated familial themes in role model stories and newsletters. In these media, we explicitly model family communication about the importance of cancer screening. Stories have included a husband reassuring his wife about the cost of a screening examination, a husband taking his wife to an appointment, and mothers encouraging their daughters and daughters convincing their mothers to get regular screening.

We did not measure other important characteristics of Mexican cultural attitudes. Attributes such as fatalismo (fatalism), religiosity (doing God's will), simpatía (being positive in all so-

cial interactions), and respeto (respect for authority) may all influence cancer-screening practices. However, Hazuda et al. (23) report that some of these attributes were so universally held among Mexican-Americans in San Antonio that scales measuring these attitudes detected no variation within the Mexican-American population. The influence of these intrinsic attributes, such as doing God's will, outlooks that emphasize luck and living for the present, and fatalistic attitudes about health, should be studied in comparison to non-Hispanic populations. In a study of Latinos in California, Pérez-Stable et al. (36) found that misconceptions about cancer consistent with fatalismo attitudes were more prevalent among Latinos than among Anglos, irrespective of education level and access to health care. Future studies of acculturation and cancer control practices in Hispanics must venture beyond the mere measurement of language use. Useful contributions can be made regarding other cultural dimensions such as fatalismo or respeto either by developing valid scales, by examining their relationship to cancer-screening practices, or by testing cancer control strategies based on these cultural dimensions.

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# Screening Practices and Knowledge, Attitudes, and Beliefs About Cancer Among Hispanic and Non-Hispanic White Women 35 Years Old or Older in Nueces County, Texas

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A telephone survey was conducted among women 35 years old or older in Nueces County, Tex., to assess ethnic differences between Hispanic and non-Hispanic white women in self-reported cancer-screening practices and knowledge, attitudes, and beliefs about cancer and to evaluate the effect of ethnicity as a predictor for screening practices. A total of 233 Hispanic and 332 non-Hispanic white women participated in the survey. Hispanics were younger and had lower educational and income levels. Overall, Hispanics had lower rates than did non-Hispanics of lifetime mammography (65% versus 79%), clinical breast examination (86% versus 96%), monthly performance of breast self-examination (37% versus 49%), and lifetime fecal occult blood testing (36% versus 69%). After control for confounding factors, Hispanics were still less likely to have ever had a clinical breast examination and fecal occult blood test. Our results suggest the need for more culturally sensitive health promotion efforts to improve knowledge about cancer and early detection practices among Hispanic women. [Monogr Natl Cancer Inst 18:49-56, 1995]

Hispanics are the largest and youngest minority group in the United States. From 1980 to 1992, the Hispanic population increased by 65%, from 14.6 million to more than 24.1 million (1). Approximately 60% of all U.S. Hispanics are of Mexican origin, but a marked increase in immigration to the United States from Central and South American countries was observed during the last decade (1). The majority of the U.S. Hispanic population resides in only two states, Texas and California (1). Almost 80% of Hispanics live in urban areas and have incomes below the poverty line. Compared with non-Hispanics, Hispanics have a lower educational level and higher rates of unemployment and more frequently lack health insurance and access to adequate health care (2,3).

Overall, lower cancer incidence and mortality rates have been documented among Hispanics than among non-Hispanics. Hispanics have lower rates of breast, colon, prostate, skin, and lung cancers; however, they have higher rates of cervical, stomach, gallbladder, and liver cancers (4-8). In Texas, breast cancer incidence and mortality rates are nearly 40% higher among non-

Hispanic whites than among Hispanics, whereas Hispanics have cervical cancer incidence and mortality rates about two times higher than those for non-Hispanic whites (9). Although ethnic differences in cancer incidence and mortality have remained over time, in some populations the gap between Hispanics and non-Hispanics is narrowing. For example, among New Mexico residents, mortality rates for several types of cancer showed a greater increase among Hispanics than among non-Hispanics from 1958 to 1987 (4). Similarly, incidence rates for breast cancer among New Mexican women increased by 56% for Hispanics but only 15% for non-Hispanic whites from 1969 to 1987 (7). The reasons for these increases have not been identified, but lack of access to health care, lack of health insurance, delay in early diagnosis, or other environmental and cultural factors may partially contribute (2-4,7).

Because of socioeconomic and cultural differences, Hispanics may encounter more barriers to use of health care services. Several studies (10-14) have shown differences between Hispanics and non-Hispanics in utilization of health services. Overall, Hispanics are less likely to have routine medical examinations, dental care, prenatal care, family planning, Pap smears, and mammography. This pattern of underutilization may not be solely explained by economic and educational barriers but may also be partially influenced by cultural characteristics (15-18). Pérez-Stable et al. (18) reported that Hispanics are less likely to obtain recommended cancer-screening services even when financial barriers are taken into account. Furthermore, Hispanics have been reported to have less knowledge about cancer preventive practices (19) and to have greater misconceptions about the causes of cancer and the effectiveness of preventive measures (20).

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See "Notes" section following "References."

Approximately 4 million Hispanics live in Texas; most live in the southern region of the state. A recent report by the Texas Hispanic Information Initiative for Good Health (21) stated that residents of south Texas have important barriers to medical care, such as urban isolation, rural distances, poor public health, and lack of insurance coverage. These and other factors may impact use of cancer-screening services in south Texas. To assess ethnic differences between Hispanic and non-Hispanic white women in self-reported cancer-screening practices and knowledge, attitudes, and beliefs about cancer and to evaluate the effect of ethnicity as a predictor for screening practices, we conducted a telephone survey in Nueces County, Tex., among women 35 years old or older.

## Subjects and Methods

### Study Population

Nueces County was selected because it provided a large, stable, urban population (291 145 in 1990, with more than 90% residing in the Corpus Christi area) comprising primarily two ethnic groups (approximately 52% Hispanic whites [mostly Mexican-Americans] and 43% non-Hispanic whites).

A computer-assisted telephone survey of a random sample of all households with telephones was conducted from October 6, 1992, through November 16, 1992, targeting Hispanic and non-Hispanic white women 35 years old or older. A total of 2450 telephone numbers were dialed (49 replicates or groups of telephone numbers, each one composed of 50 telephone numbers), resulting in 1420 (58%) calls to residential numbers. Of these, 753 (53%) calls identified a potentially eligible woman. Six hundred one (80%) women consented to participate and completed an interview. Later, 36 (6%) completed surveys were excluded on the basis of their participant's racial/ethnic group (African-American or Asian). The final study sample consisted of 565 white women: 233 Hispanics and 332 non-Hispanics.

### Survey

Data were collected on 75 items, including demographic characteristics; knowledge, attitudes, and beliefs about cancer; access to health care; prevalence of past use of screening tests for cervical cancer (Pap smear), breast cancer (mammography, clinical breast examination [CBE], and breast self-examination [BSE]), and colorectal cancer (fecal occult blood test [FOBT] and sigmoidoscopy); smoking habits; family and personal history of cancer; sources of information about cancer; and language use (Hispanics only). Knowledge, attitudes, and beliefs were assessed with a Likert-type scale, and responses were dichotomized to the following categories for statistical analysis: 1) strongly agree/agree versus disagree/strongly disagree, 2) very much/somewhat versus very little/not at all, 3) a lot/some versus very little/not at all, and 4) very good/good versus not very good/not good at all.

### Statistical Analyses

For the statistical analyses, all variables were dichotomized. Bivariate relationships between ethnicity and variables of interest were tested for independence using Pearson's chi-squared test or Fisher's exact test. Further, the relationships between ethnicity and these variables were analyzed by two age strata (35-49 years and 50 years old or older). Multivariate logistic regression models were used to assess the independent effect of ethnicity (non-Hispanic = 0; Hispanic = 1) on screening practices. Dependent variables were having ever had a Pap smear, mammography, CBE, BSE, FOBT, or sigmoidoscopy (never = 0; ever = 1) and having had a Pap smear or mammography within the year prior to the study (no = 0; yes = 1). Covariates in the logistic models included age (35-49 years = 0; ≥50 years = 1), marital status (other = 0; married = 1), education (≤high school = 0; >high school = 1), employment (no = 0; yes = 1), and health care plan (no = 0; yes = 1). Analyses of FOBT and sigmoidoscopy use were restricted to women 50 years old or older, while analyses of all other screening practices included all women.

## Results

### Demographic Characteristics

Forty-one percent of the respondents were Hispanics. Overall, the median age of respondents was 49 years (range, 35-89 years). Demographic characteristics of the respondents by ethnic group are presented in Table 1. Compared with non-Hispanics, Hispanics were younger ( $P = .004$ ) and had lower educational levels ( $P \leq .001$ ) and annual family income ( $P \leq .001$ ). An annual family income of less than \$10 000 was reported by 30% of Hispanics but only 7% of non-Hispanic whites. A higher proportion of Hispanic women were homemakers (32%), whereas a higher proportion of non-Hispanic whites were retirees (24%). Most Hispanics (68%) preferred using English for the interview. Of the Hispanic respondents, 92% were of Mexican background, and most of them (87%) were born in the United States.

### Access to Health Care

Overall, 86% of the respondents had some kind of health care plan (private insurance, Medicare, Medicaid, or coverage for military personnel, veterans, or migrant workers). Fig. 1 shows the difference in access to health care by ethnic group. Non-Hispanics were more likely to have a health care plan than were Hispanics ( $P \leq .001$ ); this ethnic difference was of greater mag-

**Table 1.** Demographic characteristics by ethnic group for participants in the Corpus Christi Cancer Study (Nueces County, Tex., 1992)\*

Characteristic	Hispanic (n = 233), %	Non-Hispanic white (n = 332), %	P
Age, y			
35-39	25	18	
40-49	34	29	
50-64	28	29	
≥65	13	25	.004
Marital status			
Married	70	72	
Divorced/separated	16	15	
Widowed	12	12	
Never married	2	1	.790
Educational level			
<High/technical school	41	13	
High/technical school	33	30	
Some college	17	27	
≥College	9	30	<.001
Income, U.S. dollars			
<10 000	30	7	
10 000-19 999	20	14	
20 000-29 999	14	20	
30 000-49 999	24	29	
≥50 000	11	29	<.001
Current employment status			
Employed/self-employed	46	49	
Homemaker	32	25	
Retired	14	24	
Unemployed/student	8	2	<.001
Language of interview			
English	68	100	
Spanish	28		
Both English and Spanish	4		

\*Because of rounding, sometimes percentages do not add to 100%.



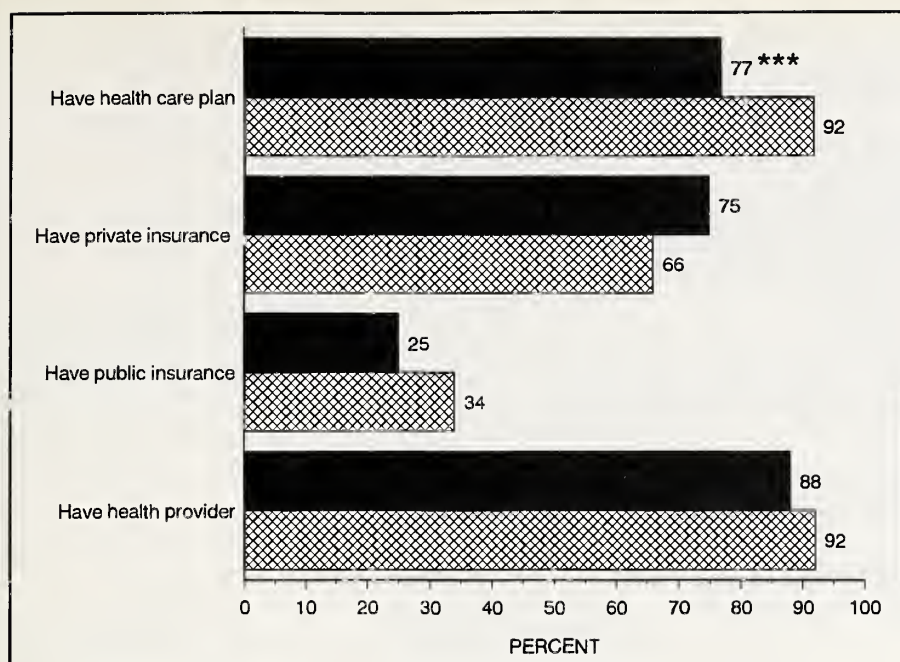


Fig. 1. Access to health care among Hispanic women (solid bar) and non-Hispanic white women (hatched bar), Corpus Christi Cancer Study (Nueces County, Tex., 1992). \*\*\* $P \leq .001$ .

nitude among older women (Table 2). Private health care was the most common type of health care plan reported by all respondents. Slightly more Hispanics (75%) than non-Hispanics (66%) reported having a private health care plan ( $P = .052$ ). Statistically significant differences in type of health care plan by age were observed: Younger women were more likely to have a private health care plan than were older women ( $P \leq .001$ ). Most respondents had a particular person or place to obtain health care or advice, and no differences were observed by ethnic group. A slightly larger proportion of non-Hispanics than Hispanics reported having a health care provider (Fig. 1 and Table 2).

### Health Knowledge, Attitudes, and Beliefs

Strong statistically significant differences between Hispanics and non-Hispanics were detected for three of the seven items concerning health knowledge, attitudes, and beliefs (Fig. 2). Hispanics were more likely than non-Hispanics to strongly agree or agree that illness is a matter of chance or fate ( $P \leq .001$ ) and that the ability to recover faster or sooner from an illness is

a matter of luck ( $P \leq .001$ ) and to have a lot or some fear of getting cancer ( $P \leq .05$ ). Among older respondents, a larger ethnic difference was observed for the belief that the ability to recover faster or sooner from an illness is a matter of luck ( $P \leq .001$ ) (Table 3). Also, Hispanic women 50 years old or older were more likely to have a fear of getting cancer than were non-Hispanic women in that age group (72% versus 58%,  $P \leq .05$ ).

### Cancer-Screening Practices

**Mammography use.** Overall, 73% of respondents reported having had at least one mammogram in their lifetime, and 69% had one within the previous year. Non-Hispanics had a higher prevalence of mammography use than did Hispanics ( $P \leq .001$ ) (Fig. 3). The lower prevalence of mammography use among Hispanics was observed for both younger and older women; however, this ethnic difference was statistically significant only among younger women ( $P \leq .01$ ) (Table 4). A slightly larger proportion of non-Hispanics than Hispanics, of borderline significance ( $P = .06$ ), had had a mammogram within the previous

Table 2. Access to health care among Hispanic and non-Hispanic white women stratified by age

	Age 35-49 y		Age $\geq 50$ y	
	Hispanic, No. (%)	Non-Hispanic white, No. (%)	Hispanic, No. (%)	Non-Hispanic white, No. (%)
Have health care plan	105 (78)	132 (89)*	71 (75)	169 (95)†
Type of health care plan				
Private	94 (89)	119 (92)	37 (53)	77 (46)
Public/federal‡	12 (11)	11 (9)	33 (47)	89 (54)
Have health care provider	119 (88)	136 (91)	84 (88)	165 (93)

\* $P \leq .05$ .

† $P \leq .001$ .

‡Including Medicare, Medicaid, and coverage for military personnel, veterans, and migrant workers.

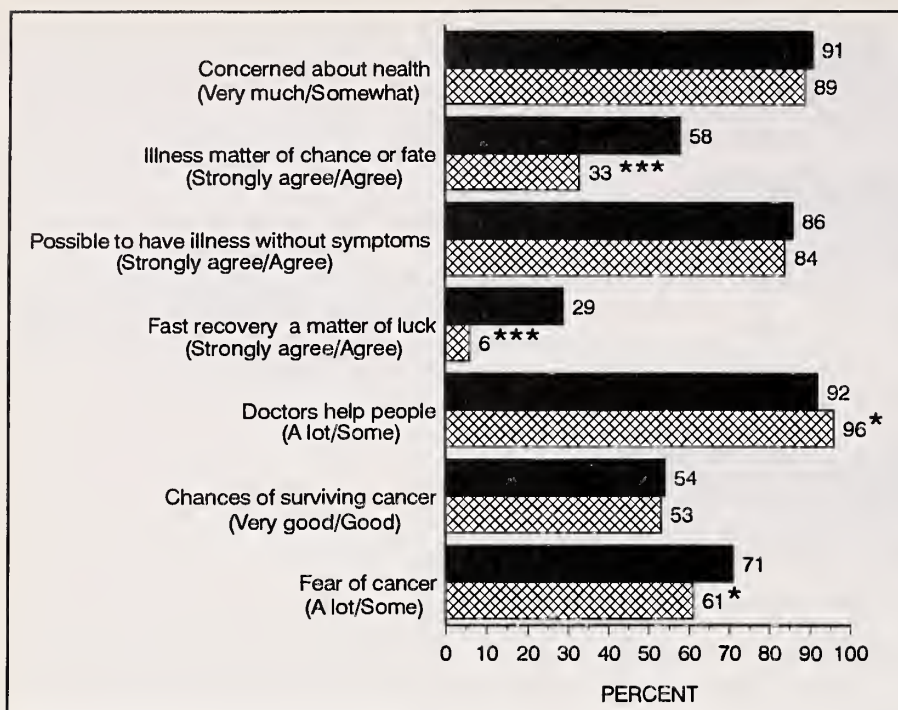


Fig 2. Health knowledge, attitudes, and beliefs among Hispanic women (solid bar) and non-Hispanic white women (hatched bar), Corpus Christi Cancer Study (Nueces County, Tex., 1992). \* $P \leq .05$ ; \*\*\* $P \leq .001$ .

year (Fig. 3); this ethnic difference was more pronounced among older women ( $P \leq .05$ ) (Table 4).

**CBE.** Most respondents (92%) reported having had a CBE at least once in their lifetime. Nevertheless, Hispanics were less likely than non-Hispanics to have ever had a CBE, regardless of age (Fig. 3 and Table 4).

**BSE.** Knowledge about BSE was reported by 94% of the respondents. A small difference in BSE knowledge was observed by ethnicity ( $P \leq .05$ ) (Fig. 3). Older Hispanics were the group with the lowest percentage of respondents who knew BSE; this percentage differed significantly from that for non-Hispanics of the same age ( $P \leq .01$ ) (Table 4). Most women reported having ever performed BSE; however, among older women, more Hispanics (95%) than non-Hispanics (87%) reported having performed BSE (Table 4).

**Frequency of BSE.** Overall, 75% of women who knew of BSE reported practicing it at least once a month. However, this category included women reporting different BSE frequency practices, ranging from seven times per day to 12 times per year. Because many of these responses do not reflect adequate knowledge of current recommendations for BSE, we decided to use a more restrictive criterion for knowledge and/or compliance with BSE recommendations. We defined a category of women who reported performing BSE "exactly once a month." This category included only women reporting performing BSE once a month and 12 times per year. On the basis of this criterion, only 44% of respondents practiced BSE monthly. Hispanic women were less likely than non-Hispanic women to practice BSE monthly ( $P \leq .05$ ) (Fig. 3). However, this difference became nonsignificant by age strata (Table 4).

Table 3. Health knowledge, attitudes, and beliefs among Hispanic and non-Hispanic white women stratified by age

	Age 35-49 y		Age $\geq 50$ y	
	Hispanic, No. (%)	Non-Hispanic white, No. (%)	Hispanic, No. (%)	Non-Hispanic white, No. (%)
Concerned about health (a lot/some)	124 (91)	138 (93)	88 (92)	153 (86)
Illness a matter of chance/fate (strongly agree/agree)	74 (56)	41 (28)*	57 (63)	63 (38)*
Possible to have illness without symptoms (strongly agree/agree)	121 (88)	125 (84)	77 (83)	149 (85)
Fast recovery a matter of luck (strongly agree/agree)	23 (17)	8 (5)†	44 (47)	8 (5)*
Doctors help people (a lot/some)	128 (96)	140 (96)	80 (86)	169 (96)‡
Chances of surviving cancer (very good/good)	70 (56)	76 (53)	40 (51)	85 (53)
Fear of cancer (a lot/some)	89 (70)	92 (65)	57 (72)	93 (58)‡

\* $P \leq .001$ .

† $P \leq .01$ .

‡ $P \leq .05$ .



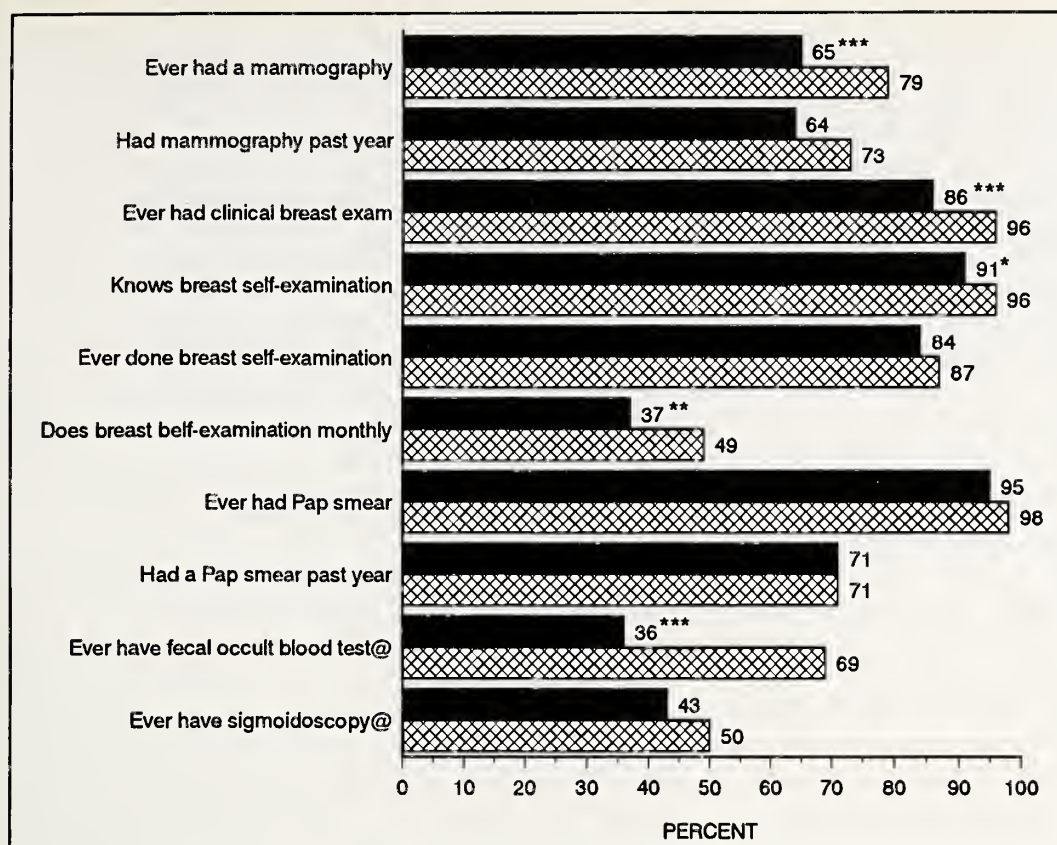


Fig. 3. Cancer-screening practices among Hispanic women (solid bar) and non-Hispanic white women (hatched bar), Corpus Christi Cancer Study (Nueces County, Tex., 1992). \* $P \leq .05$ ; \*\* $P \leq .01$ , \*\*\* $P \leq .001$ , @ women 50 years old or older.

**Pap smears.** The majority of respondents (96%) reported having had at least one Pap smear in their lifetime. No ethnic difference was detected overall (Fig. 3). A very small ethnic difference was observed among older respondents (89% for Hispanics and 96% for non-Hispanics;  $P \leq .05$ ) but not among younger respondents (Table 4). Similarly, no ethnic differences were detected in the proportion of women who had had a Pap smear within the previous year, although fewer older women in both ethnic groups reported having done so (Table 4).

**FOBT and sigmoidoscopy.** For women aged 50 years or more, 58% and 47% reported ever having had an FOBT and sig-

moidoscopy, respectively. Hispanics were significantly less likely than non-Hispanics ( $P \leq .001$ ) to have ever had an FOBT, but no ethnic differences were observed in the prevalence of use of sigmoidoscopy ( $P = .26$ ) (Fig. 3).

### Multivariate Analysis

After adjustment for age, marital status, education, employment status, and having a health care plan, ethnicity remained an independent predictor for practicing BSE monthly and for ever having had an FOBT (Table 5). Hispanics were less likely to practice BSE monthly (odds ratio [OR] = 0.66; 95% confidence

Table 4. Cancer-screening practices among Hispanic and non-Hispanic white women stratified by age

Screening practice	Age 35-49 y		Age $\geq 50$ y	
	Hispanic, No. (%)	Non-Hispanic white, No. (%)	Hispanic, No. (%)	Non-Hispanic white, No. (%)
Ever had mammography	76 (56)	106 (71)*	74 (77)	152 (85)
Had mammography within the past year	46 (61)	67 (63)	49 (66)	120 (79)†
Ever had a CBE	120 (88)	147 (99)‡	80 (84)	165 (93)†
Knows how to do BSE	129 (95)	145 (97)	79 (84)	169 (95)*
Has ever done a BSE	122 (95)	140 (97)	75 (95)	147 (87)
Practices BSE once a month	45 (38)	65 (46)	25 (34)	68 (44)
Ever had a Pap smear	132 (99)	149 (100)	84 (89)	171 (96)†
Had a Pap smear within the past year	98 (71)	115 (77)	53 (65)	111 (65)
Ever had an FOBT	50 (37)	63 (43)	33 (36)	121 (39)‡
Ever had a sigmoidoscopy	32 (24)	30 (20)	40 (43)	88 (50)

\* $P \leq .01$ .

† $P \leq .05$ .

‡ $P \leq .001$ .

interval [CI] = 0.44-1.00) and to have ever had an FOBT (OR = 0.32; 95% CI = 0.18-0.58). Increasing age was positively associated with ever having had mammography (OR = 2.64; 95% CI = 1.66-4.19) and marginally associated with having had mammography within the previous year (OR = 1.65; 95% CI = 0.98-2.77), whereas increasing age was negatively associated with ever having had a Pap smear (OR = 0.14; 95% CI = 0.03-0.70), with ever practicing BSE (OR = 0.39; 95% CI = 0.21-0.71), with having had a Pap smear within the previous year (OR = 0.60; 95% CI = 0.39-0.94), and with knowledge of BSE (OR = 0.37; 95% CI = 0.16-0.86). Married women were more likely to have ever had a Pap smear (OR = 8.39; 95% CI = 2.67-26.41), to have had a Pap smear within the previous year (OR = 1.82; 95% CI = 1.20-2.76), and to have knowledge of BSE (OR = 2.12; 95% CI = 1.03-4.34). Respondents with more than a high school education were more likely to have ever had a CBE (OR = 2.56; 95% CI = 1.10-5.93) and marginally more likely to have knowledge of BSE (OR = 2.40; 95% CI = 0.96-6.0). Having a health care plan was significantly associated with ever having had mammography (OR = 2.38; 95% CI = 1.42-3.99) or an FOBT (OR = 2.69; 95% CI = 1.05-6.9) and with having had a Pap smear within the previous year (OR = 1.74; 95% CI = 1.01-2.98).

## Discussion

This study compared cancer-related knowledge, attitudes, beliefs, and screening practices between Hispanic and non-Hispanic women 35 years old or older in Nueces County, Tex. Overall, our findings on Pap smear, CBE, and BSE practices are consistent with national data (22-24). Although mammography use in our study group was higher than most national figures (22-24), these data are consistent with the most recent data from the mammography attitudes and usage study (MAUS) for women aged 40 years or older (79% in our study [data not shown] and 74% in MAUS) (25). Higher prevalence of lifetime FOBT and sigmoidoscopy was also observed among respondents in Nueces County than in previous studies (26,27). Our bivariate analysis revealed statistically significant ethnic differences in self-reported access to health care, health beliefs, and breast and colorectal cancer-screening practices. Hispanic women were less likely than non-Hispanic women to know of

BSE, to perform BSE monthly, and to have ever had a CBE, a mammogram, and an FOBT. After adjustment for sociodemographic variables, Hispanics were still less likely to practice BSE monthly and to have ever had an FOBT.

In the United States and South Texas, approximately 33% and 30% of Hispanics, respectively, are estimated to lack health insurance (21). Our study found fewer women without access to health care, but our data on ethnic differences are consistent with national and state data. Although Hispanic respondents were less likely to have a health care plan than were non-Hispanics, no statistically significant ethnic differences in type of health care plan or in access to a health care provider were seen. The ethnic difference in the level of health insurance coverage may explain differences in health knowledge and cancer-screening practices by decreasing access to health education materials and programs and to early detection services.

A higher proportion of Hispanics than non-Hispanics had some erroneous understanding of cancer and were afraid of the disease. Hispanic women, particularly those 50 years old or older, were more likely to believe that illness is a matter of chance or fate and that fast recovery from illness is a matter of good luck. Similarly, Hispanic respondents were more likely to fear cancer than were non-Hispanic women. These beliefs about disease and the fear of cancer among Hispanics are consistent with the cultural concept of fatalism, which may determine the way Hispanics act to prevent disease or to handle health problems (20).

Comparisons between previous studies and our present study are difficult because of the different age groups included in the study populations and because of the increase in cancer-screening awareness, particularly for screening mammography, during the past decade. Nevertheless, most studies have shown a lower rate of lifetime and recent use of mammography among Hispanic women than among non-Hispanic women. Pérez-Stable et al. (18) observed a significant difference in the rate of ever having had mammography between Latino and Anglo women 35 years old or older (76% versus 85%). However, after control for age, education, employment, marital status, place of residence, and perceived health status, ethnicity was not found to be an independent predictor for ever having had a mammogram (OR = 0.76; 95% CI = 0.48-1.21) or having had mammography in the past 2 years (OR = 0.76; 95% CI = 0.51-1.12).

**Table 5.** Crude and adjusted ORs for ethnicity (Hispanic) as predictor of cancer-screening practices among women 35 years old or older

Screening practice	Crude OR	Adjusted* OR	95% CI	P
Ever had mammography	0.49	0.71	0.47-1.08	.11
Had mammography within the past year	0.66	0.73	0.46-1.18	.20
Ever had a CBE	0.45	0.39	0.19-0.79	.01
Knows how to do BSE	0.42	0.49	0.22-1.06	.07
Has ever done a BSE	0.79	0.79	0.46-1.38	.41
Practices BSE once a month	0.61	0.66	0.44-1.00	.05
Ever had a Pap smear	0.45	0.43	0.14-1.31	.14
Had a Pap smear within the past year	0.99	1.04	0.68-1.58	.86
Ever had an FOBT†	0.26	0.32	0.18-0.58	<.001
Ever had a sigmoidoscopy†	0.75	0.79	0.45-1.40	.42

\*Adjusted for age (35-49 y = 0; ≥50 y = 1); marital status (other = 0; married = 1); education (≤high school = 0; > high school = 1); employment (no = 0; yes = 1), and health plan (no = 0; yes = 1).

†Among women aged 50 years or older. ORs adjusted for marital status, education, employment, and health plan.



Elder et al. (16) also observed significant differences in the prevalence of lifetime mammography and use of mammography in the past year between Latino and Anglo women aged 50 years or older. They found ethnic differences to be associated with the level of acculturation: Less acculturated Latino women had the lowest percentage of ever having had mammography (27%) and having had mammography within the past year (16%), followed by highly acculturated Latino women (58% and 38%, respectively) and Anglo women (80% and 52%, respectively). Lower rates and smaller ethnic differences were observed by Saint-Germain and Longman (11): 51% of Hispanic and 55% of Anglo women 50 years old or older reported ever having had mammography, while only 32% of Hispanics and 36% of Anglos had had mammography in the past year. In south Texas, 45% of Hispanic women 40 years old or older in Corpus Christi and 35% of Mexican-American women of the same age living in El Paso reported ever having had mammography (9).

Similar to other studies (11,12,16,18,28), we found that women from both ethnic groups had a high prevalence of lifetime CBE, a high prevalence of lifetime BSE, but a low prevalence of monthly performance of BSE. Pérez-Stable et al. (18) reported similar proportions of lifetime CBE, knowledge of BSE, lifetime BSE, and monthly BSE to those observed in our study; however, no ethnic differences were apparent in their data after adjustment for sociodemographic variables. Similarly, after controlling for confounding factors, Elder et al. (16) did not find a statistically significant difference in the prevalence of CBE between less acculturated and highly acculturated Latino women and Anglo women aged 40 years or older.

Lifetime Pap smear and recency of Pap smear in our study were comparable to data reported by Pérez-Stable et al. (18). Lower rates have been reported in other studies that included populations of different age groups (14,16). Elder et al. (16) found that less acculturated and highly acculturated Latino women 18 years old or older had significantly lower percentages of lifetime Pap smear than did Anglo women, even after controlling for confounding factors (73% in less acculturated Latinos, 83% in highly acculturated Latinos, and 97% in Anglos). Also, data from the 1987 National Health Interview Survey showed that 80% of Hispanic women 18 years old or older compared with 93% of non-Hispanic women reported having ever had a Pap smear (14).

We found no ethnic differences in recency of Pap smear use. However, the proportion of respondents who had had a Pap smear in the past year was lower (65%) among women at higher risk for cervical cancer (50 years old or older). Using data from the 1987 National Health Interview Survey, Calle et al. (14) did not observe a statistically significant difference in recency of Pap smear use between Hispanic and non-Hispanic white women aged 18 years or older, but the proportions of women reporting having had a Pap smear in the past year were much lower than those observed in our study (35% Hispanics and 38% non-Hispanic whites). Pérez-Stable et al. (18) also failed to identify ethnic differences in recency of Pap smear use. Eighty-seven percent of Latino women and 88% of Anglo women reported having had a Pap smear within the past 3 years. In contrast, Elder et al. (16) observed a significantly lower proportion of Latino than Anglo women who reported having had a Pap

smear in the past year. Furthermore, a lower proportion of less acculturated Latinos (44%) than highly acculturated Latinos (60%) and Anglos (77%) reported having had a Pap smear in the past year. The Texas Department of Health reported that, among Hispanic women 40-70 years old surveyed in Corpus Christi, only 53% had had a Pap smear within the past year, while only 46% in El Paso had had a Pap smear within the past 2 years (9).

Our data show a very low prevalence of screening for colorectal cancer, although the lifetime use of colorectal cancer-screening tests was higher among respondents in Nueces County than reported in three earlier studies (18,26,27). In our study (data not shown), the rate of lifetime FOBT use for women aged 40 and older was 53%, whereas Pérez-Stable et al. (18) found 49% in San Francisco and Alameda Counties, Polednak (26) found 37% in Long Island and 36% in Connecticut, and the American Cancer Society's 1982 survey of a probability sample of U.S. households found 44% (27). Hispanics were even less likely than non-Hispanics to have ever had an FOBT; this difference remained after adjustment for potential confounding variables. Pérez-Stable et al. (18) found a smaller but statistically significant difference in lifetime FOBT use between Latino and Anglo women (46% versus 54%) than the one observed in our study. As in our study, this ethnic difference persisted after adjustment for potential confounding factors. Lifetime use of sigmoidoscopy among women 50 years old or older was higher in our study than in the San Francisco Bay Area (47% versus 33%) (18). No ethnic difference in lifetime sigmoidoscopy use was detected in our data, whereas in the San Francisco Bay Area, a statistically significant difference was observed between Latino (29%) and Anglo (41%) women, and this difference remained after control for confounding factors (18).

In the present study, several limitations must be considered in interpreting the results. First, telephone surveys are subject to bias, despite the high response rate (80%) in this study. Although telephone coverage in the United States is greater than 93% (ranging from 90% in the southern states to 95% in the north central states), a higher proportion of the socially disadvantaged population is not accessible by telephone (29). Among non-telephone households, there is an over-representation of minority groups and families with low income and low educational levels. This may partially explain the lower percentage of Hispanics in our study sample (41%) than in the general population (52%) and the higher rate of positive screening behaviors observed in our study, but it does not explain the ethnic differences in access to health care and screening practices that we found. Furthermore, our study sample had a high proportion of Hispanic women of low educational and low income levels; these women are considered to be at higher risk for poor screening practices.

The second limitation of the study is that our data are based on self-reported information and could not be validated, given the confidential nature of the survey. (Name and address of respondents were not recorded.) Several studies have shown that self-reported screening behaviors are overestimated (30-33). Overestimation appears to be associated with age, race, educational level of the respondent, and timing of the procedure. Gordon et al. (30) concluded that self-reporting overestimates the screened population, but concordance is observed between self-



reported and medical record information for tests in which a diagnostic report is generated (Pap smear, mammography, FOBT, and sigmoidoscopy), whereas lower concordance is observed for procedures that generate only a physician's note (CBE and digital rectal examination).

The third limitation of this study is that collected information did not distinguish between diagnostic and screening procedures, which may result in an overestimation of screening behaviors in this population. There is no reason to believe, however, that this misclassification would have been different between ethnic groups, and it is very unlikely that it would explain the lower rates of screening observed among Hispanic women.

Finally, most Hispanics in Nueces County were born in the United States, and most are of Mexican background; it is possible that the results from this study may not be generalizable to Hispanic populations of different ethnic background or to those born outside the United States.

Despite these limitations, our data show that most respondents had access to a health care plan and had high rates of most screening practices except screening for colorectal cancer. Screening practices were lower among Hispanics, and most of these ethnic differences appeared to be explained by sociodemographic factors and access to health care. However, lower rates of lifetime CBE, monthly BSE, and lifetime FOBT persisted after controlling for confounding variables.

Hispanics were more likely to have misperceptions about cancer and to have a greater fear of cancer. They also had lower educational and income levels and were less likely to have a health care plan. These findings and other cultural characteristics may contribute to the lower rates of screening practices observed among Hispanics. These data suggest that there is still a need for health promotion efforts to improve knowledge about cancer and early detection practices, especially among Hispanic and older women. These efforts must be culturally sensitive to be accepted and should address barriers as perceived by the target population. In addition, cancer-related knowledge, attitudes, and screening behaviors should be continually monitored to evaluate our progress in cancer prevention and control.

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# Beliefs, Knowledge, and Behavior About Cancer Among Urban Hispanic Women

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As part of a cancer prevention program aimed at minority and disadvantaged urban women, cancer beliefs, knowledge, and behaviors were assessed among home-health attendants in the Bronx, N.Y. Information was gathered from 876 Hispanic women who comprised 62% of the female home-attendant study population from whom data were collected ( $n = 1413$ ). Of these women, 82% ( $n = 718$ ) were Spanish speaking and 18% ( $n = 158$ ) were English speaking as defined by their choice to complete the survey questionnaire in Spanish or English. As a whole, the population reported high levels of obtaining screening tests and engaging in preventive behaviors. However, nearly 60% did not know what cervical cancer was. The most important predictor of inadequate cancer screening was lack of knowledge. Large numbers of women subscribed to cancer misconceptions, such as the belief that bumps or bruises cause cancer. Fifty-eight percent believed that surgery causes cancer to spread, a belief that may prevent a woman with breast cancer from undergoing early intervention procedures, such as lumpectomy. This survey indicated that Hispanic women in our population engaged in relatively high levels of cancer preventive behaviors, even though their knowledge base was limited. Many of them hold misperceptions about cancer that can have an impact on preventive behaviors. We conclude that cancer prevention programs targeting the Hispanic populations should emphasize the provision of factual information about cancer and cancer-screening behaviors in the context of an exploration of inaccurate beliefs about cancer that may inhibit preventive health behaviors. [Monogr Natl Cancer Inst 18:57-63, 1995]

As part of a cancer prevention program aimed at increasing knowledge about breast and cervical cancers among disadvantaged women to improve cancer-screening behaviors, cancer beliefs, knowledge, and behaviors were assessed among predominantly black and Hispanic urban women.

Ethnic minority and disadvantaged populations in the United States experience higher incidence of and mortality rates from cancer than the general population (1,2). Among cancers specific to women, rates of cervical cancer for black and Hispanic women are twice as high as those among white women (3,4). Hispanic women are less likely than white or black women to have heard of Pap smears or to be in compliance with screening guidelines (5,6). Hispanic women with low income levels also are at risk for mammography underuse (5,7). Among the barriers that have been suggested as important in hindering

Hispanic women from obtaining Pap tests and mammograms are demographic factors, such as low income, and personal factors, such as embarrassment and fear (5-9). It has been suggested that the most important barrier to reaching Hispanics is their great fear of cancer (9). Cultural beliefs about health and health care are also important determinants of health behaviors (9-13). For example, the belief that cancer is fatal and untreatable has been reported as high among Hispanic populations (5,9,14). The important role of beliefs in preventive behaviors is demonstrated by the fact that when beliefs are based on incomplete or erroneous information, inappropriate health behaviors may follow (15).

To address these problems, a culturally sensitive cancer prevention program was developed, in English and Spanish, to increase cancer knowledge as well as to improve attitudes and behaviors regarding preventive health care among underserved urban women. A survey of the study population's base-line beliefs, knowledge, and behaviors about cancer was part of this program. This article uses data gathered from this survey to describe cancer beliefs, breast and cervical cancer knowledge, and breast and cervical cancer-screening behaviors (including barriers to obtaining Pap tests and mammograms). We also use these data to examine the relationship between demographic, knowledge, and belief variables and cancer-screening behaviors among Hispanic women in the study population.

## Methods

### Study Sample

The population from which our sample was drawn were home-health attendants (in training and active) in New York City. According to a New York State Department of Social Services report, 90% of New York City home health care workers belong to minority groups. About two thirds of New York City home health care workers are born outside the continental United States. Most are born in Caribbean countries, such as the Dominican Republic, Haiti, and Jamaica, and 49% have less than a high school education (16).

The study population consisted of 876 English- and Spanish-speaking Hispanic home-attendant women who participated in a 1-week training course for home attendants offered in the Bronx, between August 1, 1993, and September 1, 1994, and all Hispanic home attendants (English and Spanish speaking) who attended in-service training courses for home attendants between April 1 and September 1, 1994.

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See "Note" section following "References."



Fifteen hundred fourteen home health workers and attendants-in-training completed questionnaires as of September 1994. Of this number, 90% were women and 10% were men. Of the 1418 women in the sample, 31% ( $n = 444$ ) were black and 62% ( $n = 876$ ) were Hispanic. This article reports analyses only on the 876 Hispanic women in the sample.

## Data Collection Instrument

The first step in the construction of the questionnaire consisted of conducting semistructured interviews with individual home-attendant trainees and holding focus groups with groups of 15 home health attendants-in-training to identify general knowledge, perceptions about health, attitudes about cancer and cancer screening, and health care habits and behaviors. From these discussions, several areas emerged as important: the need for basic information about cancer and cancer screening, beliefs and misconceptions about cancer, dietary habits and nutrition and their relationship to cancer prevention, and a sense of personal control over one's health. With the use of information gathered from the interviews and focus groups, we constructed a 2-hour curriculum. Once the curriculum content was established, we went back and devised questions that covered the topics contained in the curriculum. This approach to questionnaire development—constructing items to assess knowledge, attitudes, and behaviors in areas to be covered by the cancer prevention course—was employed so that post-testing 1 year later might help evaluate if the course improved knowledge, attitudes, or behaviors. The data collection instrument, however, was also construed as a one-time survey of the knowledge, beliefs, and behaviors of the study population.

Questionnaire items originally were developed in English and translated into Spanish with the use of back-translation techniques (17). Items were constructed to cover five general domains: demographics, general health habits (e.g., smoking, drinking, and exercise), breast and cervical cancer knowledge and screening behaviors (including barriers to obtaining screening tests), basic nutrition information, and beliefs about cancer and disease. Questions on beliefs addressed attitudes, perceptions, and misperceptions about cancer. All items were originally designed to be answered in a dichotomous fashion (yes/no), except for two open-ended questions.

The National Institutes of Health literacy formula (SMOG) was applied to sections of the questionnaire to test for literacy level (18). The SMOG formula involves counting the number of polysyllabic words to determine grade level. This method revealed a 9th-grade reading level; consequently, items were reworded to eliminate as many polysyllabic words as possible. The SMOG formula was applied to the questionnaire's latest revision and a 7th-grade reading level was determined.

The questionnaire was pilot tested with 40 English- and 40 Spanish-speaking home attendants-in-training. Verbal feedback was solicited from those answering the questionnaire about understandability and clarity as well as level of discomfort in answering the questions. Based on respondents' feedback, ambiguous, redundant, and difficult items were reworded or eliminated. After respondents reported feeling constrained by yes/no answers, questions regarding perceptions and beliefs were revised to include four response options (Likert scale). Finally, items that did not perform well in the Spanish-speaking group (e.g., culturally insensitive or inaccurately phrased items) were reworded and then translated back into English using back-translation techniques.

The final instrument covered the following areas: demographics and health history; health habits, including smoking, drinking, and exercise; cancer knowledge and screening behaviors, including barriers to screening tests; nutrition and diet; and beliefs about disease in general and cancer in particular, including health locus of control. Two open-ended questions included in the questionnaire asked the respondents to write their own ideas about how people get cancer and how people get sick in general.

Demographic variables assessed by the questionnaire included age, sex, language, ethnicity, country of origin, religion, education, marital status, number of children, and health history. Cancer knowledge questions included knowing what cervical cancer is, what a Pap test is, what breast cancer is, and what a mammogram is. Reported barriers to obtaining Pap smear tests and mammograms were collapsed into a single-barrier score. These scores were based on 14 Pap smear test barrier choices and 13 mammography barrier choices selected as reasons for not obtaining a test. The barrier score became a dichotomous variable of "Yes" or "No," reflecting whether or not at least one barrier was indicated. Overall barrier scores were developed after an examination of the relationship between each individual barrier choice, and other individual variables revealed that correlations were relatively similar among individual barrier choices. Beliefs were measured using Likert scales and included items that as-

sessed perceptions about cancer (e.g., is it curable?) and misperceptions about cancer (e.g., a bump or hard knock can cause cancer). Screening behaviors were measured by self-reported response to the following questions: have you ever had a Pap test; have you ever had a breast examination done by a doctor; have you ever examined your own breasts looking for lumps; and have you ever had a mammogram? The questionnaire also included a six-item adaptation of the Multidimensional Health Locus of Control scale for Hispanic populations (12).

## Data Analysis

Descriptive statistics were used to compute frequency of response for all demographic items and all questions about cancer beliefs, knowledge, barriers, and screening behaviors. For purposes of analysis, an overall Pap test barrier and mammogram barrier score was computed. To examine the relationship of cancer knowledge and beliefs to health behaviors, Pearson product-moment correlations were computed to determine significant correlations among variables; regression analyses were then performed to examine the extent to which demographic factors, knowledge, and beliefs about cancer significantly predicted screening behaviors. In this analysis, only those independent variables that were significantly correlated among each other at the zero-order correlation level were included. Since nearly two thirds of the respondents had an educational level of less than 12 years, the education variable was dichotomized into fewer than 12 years and 12 years or more. The screening behavior variables included Pap test, breast self-examination, breast physical examination, and mammogram.

## Results

### Demographic Data

Table 1 shows the primary language, country of origin, education, marital status, religion, and importance of religion of 876 female Hispanic home-health attendants. The majority of Hispanic women in this sample were Spanish speaking ( $n = 718$ ). Respondents were designated as Spanish speaking if they completed the questionnaire in Spanish. The Dominican Republic and Puerto Rico are the most prevalent countries of origin for the study population. More than 80% of the respondents are Catholic, and 98% of the respondents report themselves as religious. The mean age of the study population was 38 years (range, 19-72). The mean number of school years completed by the study population was 10.6 ( $SD = 2.8$ ). Twenty-three percent reported they had completed eighth grade, while 31% report that they had completed high school. Forty-six percent ( $n = 411$ ) reported being married or living with someone, 33% ( $n = 293$ ) reported being divorced or separated, 3% ( $n = 25$ ) were widows, and 14% ( $n = 122$ ) had never been married. Seventy-eight percent ( $n = 681$ ) of the respondents had children.

### Knowledge and Beliefs About Cancer

When asked the question, "Do you know what cervical cancer is?" 58% ( $n = 507$ ) of the women answered "no," yet 90% ( $n = 791$ ) reported that they knew why a Pap test was done. Similarly, when asked "Do you know what breast cancer is?" 40% ( $n = 354$ ) reported no, while 88% ( $n = 769$ ) reported that they knew what a mammogram was. In response to the question "How often should a woman get a Pap test?" 61% ( $n = 536$ ) reported every 6 months, while 37% ( $n = 322$ ) reported every year.

Three questions addressed beliefs (perceptions) about cancer. Fifty-eight percent ( $n = 504$ ) answered yes to the question, "Do you believe you will ever get cancer?"; 89% ( $n = 787$ ) answered yes to the question, "Do you believe cervical cancer is curable?"; and 89% ( $n = 776$ ) answered yes to the question, "Do you believe that early diagnosis can cure breast cancer?"



**Table 1.** Participant characteristics, Hispanic women (n = 876)\*

Characteristic	No. of women	%
Primary language		
English	158	18
Spanish	718	82
Country of origin		
Dominican Republic	457	53
Puerto Rico	177	20
Central America	109	13
United States	78	9
South America	38	4
Other	17	2
Education		
8th grade or less	205	23
Completed 9th grade	80	9
Completed 10th grade	59	7
Completed 11th grade	82	9
Completed 12th grade	271	31
Some college	139	16
Marital status		
Married	346	40
Separated	170	19
Divorced	123	14
Never married	122	14
Living with someone	65	7
Widowed	25	3
Religion		
Catholic	717	81
Protestant	108	12
Jehovah's Witness	15	2
Other	6	<1
Importance of religion		
Very important	677	77
Somewhat important	170	19
Not important	19	2
No response	10	1

\*Because of rounding and missing data, percentages may not add up to 100.

Respondents were asked to indicate agreement or disagreement to eight belief statements about cancer that are common misconceptions about cancer as viewed from a western biomedical

perspective. Responses to the statements about cancer are shown in Table 2. All the beliefs except three were subscribed to by at least one third of the women. The two misperceptions most frequently endorsed were: "it is possible for a bump or hard knock to cause cancer" (58% agreed) and "surgery can cause cancer to spread" (30% agreed). The belief that "once you get cancer, you almost always die from it" was held by 56% of respondents, while 44% of the women agreed with the statement "cancer cannot really be cured."

In addition to the information about cancer and disease beliefs as gathered through response to quantitative questionnaire items, information about perceptions of cancer etiology was obtained through an open-ended question that asked: "Do you have ideas about how people get cancer? Please write your ideas in the following space." Using qualitative methods to analyze the responses, compiled responses to each question were examined, and then several major themes were identified. Statements were assigned to thematic categories, and numbers of responses in each category were tallied. Five major thematic categories were identified from the responses: 1) carelessness/lack of prevention, 2) beliefs of harm to the body, 3) heredity, 4) body chemistry/destiny, and 5) environmental/chemical.

Table 3 shows the percentage of responses in each category as well as representative statements for each theme.

### Barriers to Obtaining Pap Tests and Mammograms

To gather information about what might prevent women from obtaining screening tests, two questions were included in the questionnaire that asked those who had never had a Pap test and those who had never had a mammogram to circle the reason or reasons why. Fourteen options were listed as responses to the Pap test barrier question, and 13 options were available for the mammogram barrier question. Only 10% (n = 84) of the total study population (n = 876) reported barriers to obtaining Pap tests. Of the respondents who reported barriers to Pap tests, 24%

**Table 2.** Cancer and disease myths (n = 876)\*

	Agree		Disagree	
	No.	%	No.	%
Cancer myth				
It is possible for a bump or hard knock to cause cancer	510	58	309	35
Once you get cancer, you almost always die of it	492	56	344	39
Cancer cannot really be cured	382	44	452	52
Surgery can cause cancer to spread	259	30	556	64
A person over 65 usually does not get cancer	258	29	567	65
Being emotional can cause cancer to spread	174	20	627	72
You can catch cancer from other people	79	9	751	86
Being a mean person can cause you to get cancer	56	6	773	88
Disease myth				
To be healthy, it is important for the body not to be too hot or too cold	499	57	301	34
If your soul is not healthy, your body won't be	488	56	322	37
The best way to cure someone with a serious disease is by a miracle	302	34	254	29
If someone wishes you harm, they can make you sick	267	31	551	63
God can punish people by making them sick	185	21	631	72
Good people usually don't get very sick	110	13	717	82

\*Because of rounding and missing data, percentages may not add up to 100.

**Table 3.** Ideas about why people get cancer\*

Idea	%
Carelessness/lack of prevention	70
By not eating right	
You get cancer out of carelessness	
Lack of personal hygiene	
If a person doesn't have check-ups	
From vices (bad habits) and also inadequate diet	
Lack of Pap smear	
Beliefs of harm to the body	20
A person can develop cancer from a hard knock	
If a woman is hit in her breast	
Cancer comes from many surgeries	
Having many children	
From a fall	
Heredity	20
Get it because it runs in the family	
It comes from one generation to another generation	
Family history	
Body chemistry/destiny	8
For some reason body cells die	
Tissue decomposition	
Some kind of biological disorder	
Weakness in the blood	
Only God knows what disease we are going to die from	
Environmental/chemical	8
Poisonous chemicals in the air or food can lead to cancer	
Asbestos and other chemicals	
It could be from any magnetic ray	
Skin cancer when taking too much sun	

\*n = 680 respondents who wrote statements.

indicated "I don't know what a Pap test is," 22% reported "my doctor never suggested it," 19% reported "I do not know how to get one," 16% indicated "I have no problems so I don't need the test," 15% reported "I have never had sex so I don't need one," and 14% stated "I meant to but I haven't gotten around to it." Nineteen percent (n = 71) of those 40 and over (n = 370) reported barriers to obtaining mammograms. Of this number, 29% (n = 40) reported "my doctor never suggested it," 17% (n = 12) stated "I have no problem," and 15% (n = 11) indicated "I meant to but I haven't gotten around to it."

After determining that individual barriers to a Pap test and mammography screening did not correlate significantly with individual demographic, belief, or knowledge variables, a dichotomous variable was created to explore whether having any barrier at all as contrasted with having none was significantly related to other variables of interest. Having a barrier to obtaining a Pap test (n = 84) was significantly correlated with being younger, not having children, not being married, not knowing what cervical cancer is, or not knowing why a Pap test is done. Having a reported barrier to getting a mammogram was strongly correlated only with knowledge of what a mammogram is.

### Cancer-Screening Behaviors

Although 87% (n = 766) of respondents reported having had a Pap test at one time, only 65% (n = 569) reported having had one in the past year. A very high number of women also reported doing breast self-examinations (82%, n = 717) and having breast examinations done by a doctor (84%, n = 739).

Among women 40 years and older, 79% (n = 293) reported having had a mammogram.

### Demographic, Knowledge, and Belief Predictors of Screening Behaviors

Pearson product-moment correlations revealed the following variables to be significantly related to screening behaviors: demographic variables (having children, religion, age, marital status, Spanish or English speaking, and educational level), knowledge (of breast and cervical cancer, of what a mammogram is, of why a mammogram is done, and of what a Pap test is and why it is done), and beliefs and misperceptions (early diagnosis improves chances of cure, "you can catch cancer from other people," "a person over 65 usually does not get cancer," "if your soul is not healthy your body won't be," and "once you get cancer you will almost always die from it").

These variables were entered in the regression analysis to determine how much variance they accounted for in predicting each screening behavior (i.e., Pap test screening, breast physical examination, breast self-examination, and mammography).

**Pap test screening.** When predicting variance in Pap test screening behavior (Table 4), demographic variables accounted for 23% of the variance in Pap test screening behavior. For this analysis, Pap test screening behavior was defined as ever having had a Pap test. The three knowledge variables (what cervical cancer is, why a Pap test is done, and why a mammogram is done) accounted for an additional 13% of the variance. Belief and myth variables did not impact on Pap test screening behavior. The strongest predictor of whether or not a woman went for a Pap test was knowledge of what a Pap test is. The second strongest predictor variable was whether or not she had children. Last, a woman's marital status and age affected whether or not she was likely to have a Pap test done.

**Breast physical examination.** Table 5 lists the significant predictors for breast physical examination. Demographic variables (age, marital status, and having children) contributed 9% of the variance for this behavior. Knowledge variables about what breast cancer is and why a Pap test is done accounted for an additional 3% of the explained variance.

**Breast self-examination.** The only significant demographic predictor of breast self-examination behavior was whether or not a woman had children, which accounted for 3% of the variance (Table 6). Knowledge of why a Pap test is done and knowledge of what breast cancer is contributed an additional 6% of the variance.

**Mammogram.** Women aged 40 and older (n = 370) were included in the mammography analysis. Age accounted for some of the variance in mammography screening behavior. Knowledge of what a mammogram is accounted for most of the explained variance (Table 7).

In general, regression analyses revealed that respondents' age and having children were powerful variables predictive of cancer screening behaviors. Knowledge of what breast cancer is, what cervical cancer is, why Pap tests and mammograms are done, and an educational level of grade 12 or above also influenced participation in screening behaviors. Holding demographic and knowledge variables constant, beliefs about cancer did not appear to impact greatly on cancer-screening behaviors.



**Table 4.** Regression analysis of demographics, knowledge, and beliefs on Pap test behavior (n = 608)

Variable	Step 1 beta	Step 2 beta	Step 3 beta	Step 4 beta
<b>Demographics</b>				
Children	.26§	.21§	.21§	.21§
Religion*	-.11	-.10	-.10	-.10
Birthdate	.21§	.13§	.13§	.13§
Marital status†	.19§	.17§	.17§	.17§
Language‡	.00	.05	.05	.05
Education	-.08¶	-.01	-.01	-.01
<b>Knowledge</b>				
What cervical cancer is		.10	.09	.09
Why a Pap test is done		.34§	.33§	.33§
<b>Beliefs</b>				
Early diagnosis can cure breast cancer			-.02	-.02
Early diagnosis can cure cervical cancer			.05	.05
A person over 65 usually does not get cancer				.001
R <sup>2</sup>	.23§	.36§	.36§	.36§
R <sup>2</sup> change		.13§	.002	.000

\*Category values: 1 = Protestant; 2 = Catholic; 3+ = other.

†Category values: 1 and 2 = married and living with someone; 3 and 4 = divorced and separated; 5 = widowed; 6 = never married.

‡Category values: 1 = English speaking; 2 = Spanish speaking.

§P&lt;.001.

||P&lt;.01.

¶P&lt;.05.

**Table 5.** Regression analysis of demographics, knowledge, and beliefs on breast physical examination behavior (n = 610)

Variable	Step 1 beta	Step 2 beta	Step 3 beta	Step 4 beta
<b>Demographics</b>				
Language*	-.01	-.01	-.001	-.001
Birthdate	.15‡	.09§	.09§	.10§
Marital status†	.08‡	.11‡	.09§	.09§
Children	.19	.17‡	.17	.17
Education	-.07	-.04	-.03	-.03
<b>Knowledge</b>				
Why a Pap test is done		.11‡	.09§	.09§
What breast cancer is		.09§	.09§	.10§
What a mammogram is		.02	-.01	-.01
Why a mammogram is done		.00	-.01	-.01
<b>Beliefs</b>				
Early diagnosis can cure breast cancer			.04	.04
Early diagnosis can cure cervical cancer			.09§	.09§
You can catch cancer from other people				-.02
God can punish people by making them sick				-.03
R <sup>2</sup>	.10	.13	.14	.14
R <sup>2</sup> change		.03	.01§	.00

\*Category values: 1 = English speaking; 2 = Spanish speaking.

†Category values: 1 and 2 = married and living with someone; 3 and 4 = divorced and separated; 5 = widowed; 6 = never married.

‡P&lt;.01.

§P&lt;.05.

||P&lt;.001.

Further analyses of the role of beliefs in preventive behaviors, which investigate interaction effects, might uncover more indirect relationships between beliefs and behaviors.

## Discussion

The intention of this exploratory study of beliefs, knowledge, and behaviors about cancer among Hispanic women was twofold: to describe cancer beliefs, knowledge, and behaviors among the surveyed population and to examine whether par-

ticular demographic, knowledge, or belief variables predicted any of the measured screening behaviors. A major purpose in gathering these data was to use this information to help build effective prevention programs for Hispanic populations based on detailed knowledge of the needs and characteristics of the population.

The women in this sample reported high levels of cervical and breast cancer-screening behaviors. Both Pap test and mammography use exceeded the New York State and national figures as reported in the Behavioral Risk Factor Surveillance

**Table 6.** Regression analysis of demographics, knowledge, and beliefs on breast self-examination behavior (n = 665)

Variable	Step 1 beta	Step 2 beta	Step 3 beta
Demographics			
Birthdate	.06	.00	.00
Marital status*	.00	.02	.02
Children	.17†	.14†	.15†
Education	.01	.03	.03
Knowledge			
Why a Pap test is done		.09‡	.08‡
What breast cancer is		.17†	.17†
What a mammogram is		.02	.02
Why a mammogram is done		.08	.07
Beliefs, early diagnosis can cure breast cancer			.03
R <sup>2</sup>	.04	.10†	.10†
R <sup>2</sup> change		.06†	.00

\*Category values: 1 and 2 = married and living with someone; 3 and 4 = divorced and separated; 5 = widowed; 6 = never married.

†P<.001.

‡P<.05.

Data (19). In examining variables associated with these reported screening behaviors, knowledge (of cervical and breast cancer) emerged as an important predictor of adequate screening, especially of Pap testing. Women who know what cervical and breast cancer are and who know what screening tests are for are more likely to get tested. Although only a small percentage of women in this sample reported barriers to obtaining Pap tests and mammograms, a strong relationship was found between lack of knowledge about cervical and breast cancers and failure to have a Pap test or mammogram in this group. This finding is consistent with other reports (20). Demographic variables also played some role in determining screening behaviors; in particular, having children made it more likely that one would be screened. Although it has been suggested that educational attainment may also be an important variable associated with preventive behaviors (21), in our sample, educational level was not strongly correlated with screening behaviors. Knowledge, rather than grade level, may be a better indicator of educational attainment for the study population.

Although knowledge was important as a predictor of screening tests, the reported knowledge about cervical and breast cancers among the women in the population was not high. Nearly 60% reported that they did not know what cervical cancer is. The question arises, if knowledge is a strong predictor of screening behaviors, why is there such a high rate of reported screening behaviors? Given the moderate knowledge level, one would expect a moderate rate of screening behaviors. A possible explanation for this finding is that being employed as a home-health attendant gives a woman more exposure to screening tests (taking their clients to doctors and having their own tests done through insurance coverage). One can engage in a preventive behavior without having explicit knowledge of what it is and what it is preventing. It is also possible that screening test behaviors are being overreported. Barriers would correspondingly be underreported. The possibility must be considered that the population's "true" screening behaviors (and thus "true" barriers

**Table 7.** Regression analysis of demographics, knowledge, and beliefs on mammography behavior (Hispanic women 40 and over; n = 370)

Variable	Step 1 beta	Step 2 beta	Step 3 beta
Demographics, birthdate	.12*	.12*	.11*
Knowledge			
What a mammogram is		.33†	.33†
Why a mammogram is done		-.01	-.01
What breast cancer is		.07	.07
Beliefs, once you get cancer you will almost always die from it			.05
R <sup>2</sup>	.01*	.16†	.16†
R <sup>2</sup> change		.15†	.01

\*P<.05.

†P<.001.

to getting screening tests) were not captured by the survey because of many issues, including trust, response set, and other threats to the validity of a self-report questionnaire.

A vivid picture of the beliefs and attitudes of the study population emerged from the survey responses. Some of these perceptions and ideas about cancer and disease causality can have direct and indirect impacts on the ways women take care of themselves and how they use the health care resources available to them. For example, the strongly endorsed belief that surgery causes cancer to spread might create reluctance among many women to discover cervical or breast cancer, which are both approached through surgical excision. Although beliefs did not predict screening behaviors, this population subscribed to a number of misconceptions about cancer that might prevent them from engaging in cancer treatments and also from wanting to know whether or not they had cancer. Although nearly 90% of the women stated that if cervical cancer is found early it is curable and that early diagnosis of breast cancer improves chances of cure, 44% agreed with the statement that cancer cannot really be cured and 56% agreed that once you get cancer you almost always die of it. This ambivalence may be a reflection of an underlying fear of cancer coupled with a strong commitment to the role of self-care activities in cancer prevention. Seventy-eight percent of the respondents chose to write down their ideas when asked why they thought people get cancer. Most of their responses clustered around the belief that they could do something to improve their health, e.g., eating correctly, going for check-ups, and being careful about cleanliness. This apparently strong "locus of control" may also explain the high level of reported screening behaviors.

Several factors may limit the generalizability of our findings. The study population was composed of home-health attendants, either in training or active. Women who seek employment as health-care workers may be more sensitive to health concerns and issues than others. Another limitation relates to the use of self-report in measuring behaviors. Self-reported screening behaviors were very high. We were unable to check medical records to determine if this reporting was accurate.

In conclusion, the picture that emerged from the survey data we have analyzed is one of a cultural group engaged in relatively high levels of preventive behaviors but a group with inade-



quate knowledge about cancer coupled with strong beliefs and misconceptions about health and disease. There is a need to provide cancer information to Hispanic women in a way that addresses underlying and powerful beliefs. Only when information is offered in the context of the cultural beliefs and expectations can it be used and translated into behavioral change.

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# Psychosocial Correlates of Smoking Among Immigrant Latina Adolescents

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Young immigrant Latinas, compared with non-Latina white adolescents, are at greater risk to begin smoking and experimenting with other substances; yet little is known about the contributing factors that place them at this risk. To identify psychosocial predictors of smoking, a sample of 447 self-identified Latinas and 160 non-Latina white adolescents aged 13-18 years from San Francisco and San Mateo counties, Calif., answered a 30-minute face-to-face questionnaire. Significant predictors of smoking status for the entire sample were (a) self-efficacy to avoid smoking (odds ratio [OR] = 10; 95% confidence interval [CI] = 5-21;  $P < .001$ ), (b) intention to smoke even if it is risky (OR = 10; 95% CI = 5-20;  $P < .001$ ), (c) usage of free time (OR = 4; 95% CI = 2-8;  $P < .001$ ), (d) personal approval of others' smoking (OR = 3; 95% CI = 1-5;  $P < .01$ ), and (e) peer's smoking approval (OR = 2; 95% CI = 1-4;  $P < .05$ ). The majority of the adolescent smokers in this study reported low levels of self-efficacy for avoiding smoking and believed that they would continue to smoke even if it was risky. They spent more of their free time with friends or alone, reported higher personal approval of significant others' smoking, and reported stronger perceived peer's approval of smoking than nonsmokers. For non-Latina whites, personal approval of others' smoking and having serious problems were associated with smoking. Predictors of smoking in the Latina sample were (a) self-efficacy to avoid smoking, (b) intention to smoke even if it was risky, (c) spending free time with friends or alone rather than with family, and (d) perceived peer's approval of smoking. Smoking was significantly associated with higher levels of acculturation toward the U.S. culture. For Latinas, spending free time with family appears to be a protective factor in preventing smoking. Peer's approval of smoking was a predictor of smoking for Latinas. The importance of these factors may be explained by the central role of the Latino family ("familismo") and the need for pleasant social relationships ("simpatía"), two of the strongest Latino culture-specific values. Tobacco educational programs targeting Latinas need to encourage parental involvement, better understanding of Latino family values, and the strengthening of social resistance. [Monogr Natl Cancer Inst 18:65-71, 1995]

Cigarette smoking has been identified as a major public health problem and the most preventable cause of premature death in the United States (1). Although efforts have been made to reduce the smoking prevalence in the general population, few

efforts have been made to prevent initiation of cigarette smoking among ethnically diverse groups such as immigrant Latina adolescents. Young immigrant Latinas, compared with non-Latina white adolescents, are at greater risk to begin smoking and experimenting with other substances; yet little is known about the contributing factors that place them at this risk. Latino youth smoke at a rate comparable to, if not greater than, that for other ethnic or racial groups (2) and are at greater risk for substance abuse, specifically, abuse of alcohol and tobacco (3-5). More Latinas are smoking as they acculturate and adopt mainstream smoking behavior, which diminishes their self-efficacy to resist further invitations to smoke (4,6-8). Increasingly, the tobacco industry is targeting Latina youth with suggestive advertisements sponsoring entertainment, cultural, and sports events that draw large minority audiences (9,10).

Nationwide, the rate of smoking among young Latinas is increasing, compared with that among young Latinos and older birth cohorts (11). Latina adolescents have a higher prevalence of ever smoking than black females (1,12) and a lower smoking prevalence than non-Latina white females (13). Results from the National Household Survey indicated that 40% of Latino male adolescents and 30% of female adolescents aged 12-17 years have also smoked cigarettes. That tendency increased to 63% for Latino males and 49% for young female adults aged 18-25 years (14). Despite the general decline in the prevalence of smoking among adults, smoking rates have declined very little for non-Hispanic white and Latino youths (1,15). By age 18, about two thirds of adolescents in the United States have tried smoking. These results suggest that the public messages stressing the avoidance of smoking initiation have not been successful in reaching adolescents, let alone Latina adolescents.

Research on the factors that place Latina adolescents at risk for initiating and continuing smoking is scarce. The processes leading to smoking are different for male and female adolescents (16), varying with culture, immigration, and acculturation levels (17). Among the psychosocial factors predicting smoking, peer and family influences have been identified as the strongest predictors of smoking among Puerto Rican youth and other Latino subgroups in the United States (18). Family pride is a

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See "Notes" section following "References."



protective factor that affects smoking and drug use by Cuban youths as well as other recently immigrated Latino youths residing in the Miami area (19).

Acculturative stress may be a mediational factor that plays a significant role in smoking initiation (17). Latina youth may conform to the mainstream adolescent culture by adopting risky behaviors such as smoking to gain acceptance from peers, which in turn increases self-esteem. Other contributing factors that may place Latinas at higher risk to initiate smoking are family disintegration (20), low social self-concept (21), poor relationship with parents, and deviant behavior, poor self-esteem, depression, sensation seeking, and peer and adult substance abuse by older siblings and parents (22-24). More information is needed about what places immigrant Latina youth at risk to initiate smoking.

This study will examine personal factors and normative expectations that place Mexican and Central American female immigrant youth at risk to initiate smoking as compared with non-Latina white adolescents. We hypothesized that there are differences in psychosocial predictors of smoking status by ethnicity and that acculturation to the U.S. mainstream may place Latina immigrants at risk to smoke.

## Methods

### Subject Selection

Respondents were 447 self-identified Latina and 160 non-Latina white adolescents between the ages of 13 and 18 years, residing in San Francisco and San Mateo counties, Calif. In this study, the term "Latino" denotes current residents of the United States, male or female, who trace their background to either a Latin American country or Spain. The term "Latinas" refers to females only. Respondents were recruited by face-to-face contact and by fliers in English and Spanish posted in the waiting rooms of 16 clinics, one public hospital, two community centers, and eight public schools. Respondents participated voluntarily and were interviewed face-to-face following carefully standardized procedures. Those interested in participating called the project assistant directly to be screened, to make an appointment to sign the consent forms, and to answer the questionnaire. Participants were paid \$10 after they completed the questionnaire, which took approximately 30 minutes. The same recruitment procedure was used for both Latina and non-Latina white adolescents. Efforts were made to recruit non-Latina white adolescents and Latina adolescents from the same sites. The difference in the number of adolescents recruited from each ethnic group reflects the unique ethnic composition of community clinics, county hospitals, and public schools of San Francisco, which is skewed toward Latino, African-American, and Asian adolescents. To avoid bias in recruitment of adolescents of both ethnic groups, recruitment was also conducted at schools and clinics in San Mateo County, where the majority of the population is non-Latino white. Interviews were bilingual Latina and non-Latina white research assistants who received 6 hours of training, which included role playing of the face-to-face and closed-ended interviewing techniques used for this study.

### Questionnaire

Questionnaire items were developed on the basis of a content analysis of responses received from an open-ended interview with 20 Latina adolescents. Focus groups were also conducted with 30 Latinas to identify knowledge and attitudes about smoking. The results of the content analysis, as well as information from the existing literature and from other standard instruments, such as the National Health Interview Survey on Teenage Attitudes and Practices (25) and Rosenberg's Self-esteem Inventory (26), were used to develop the closed-ended stems and response categories contained in the structured questionnaire. Items were developed in Spanish and were then translated into English through the back-translation procedure (27,28) and pretested in English and Spanish. The

Spanish version was also reviewed by Spanish speakers from various Latin American countries to identify and eliminate parochial wording.

The questionnaire assessed smoking status and psychosocial correlates of smoking: personal factors and normative expectations. Current smokers were defined as those who reported smoking any cigarettes within the last 7 days and were current regular or current occasional smokers.

**Measures of personal factors.** 1) Self-efficacy—Using a scale of 1 to 10, respondents were asked to rate how confident they were that they would not smoke in the next 3 months. 2) Self-esteem—The 10-item Rosenberg Self-esteem Inventory (26) was used. 3) Intention to smoke and risk taking—Two dichotomous (yes/no) items were adapted from the Eysenck Risk Taking Scale (29): "Would you try or continue to smoke cigarettes even if it is risky?" and "Do you enjoy doing things every now and then that are a little risky or dangerous?" 4) Usage of free time—Adolescents were asked to identify with whom (family or friends or alone) they spent most of their free time. 5) Emotional distress—Six items were used to measure how often adolescents were bothered by emotional problems. 6) Personal approval of significant others' smoking—Three items were asked: "How do you think you would feel about your best friend, boyfriend/spouse, and parents smoking cigarettes?" 7) Having serious problems—Adolescents were asked the question, "Have you had any serious problems in the last 30 days?"

**Measures of normative expectations.** 1) Drug and alcohol use by friends—A seven-item, three-point scale (most or all, some, or none) derived from the National Institute on Drug Abuse Household Survey (30) asked the question, "How many of your close friends do the following things: smoke cigarettes, use marijuana, PCP/Angel Dust, uppers, downers, or drink alcohol?" 2) Perceived peer approval of smoking—A dichotomous (yes/no response) item was used: "Do you believe people your age would care if their closest friend told them not to smoke?" 3) Significant others' smoking approval—The question asked concerned three items: "How do you think your (parents/best friend/boyfriend or spouse) would feel about you smoking cigarettes? (disapprove, would not care, or approve)." 4) Social smoking triggers—The following question was asked: "When do people your age usually smoke cigarettes (when partying, when drinking alcohol, and when seeing others smoke)?"

Standard demographic variables were collected. A reliable and valid five-item language-related scale (31) was included to measure acculturation. The total average was dichotomized into "more" acculturated to the U.S. culture (score of  $\geq 3$ ) and "less" acculturated (score of  $< 3$ ; i.e., high acculturation = English speaking, and low acculturation = Spanish speaking).

### Data Analyses

To describe the demographic and psychosocial factors associated with smoking status, we conducted  $\chi^2$  tests comparing smokers and nonsmokers for Latina and non-Latina white adolescents in demographic and psychosocial variables. Calculations included the proportion of responses to each of the demographic and psychosocial variables by smoking status and ethnicity. SPSS software was used to conduct statistical analyses (32). Multivariate logistic regression (33) was next used to assess psychosocial predictors of smoking behavior. Three separate logistic regressions were performed: one for non-Latina whites, another for Latinas, and a third for the entire sample. Only variables that were statistically significant predictors of smoking status were included in the final model to achieve the most parsimonious one. The final model included six psychosocial variables: 1) self-efficacy, 2) personal approval of significant others' smoking, 3) usage of free time, 4) having a serious problem, 5) intention to smoke even if it is risky, and 6) peer's approval of one's smoking. In each analysis, the predictor variables were entered simultaneously into the model. The dichotomous outcome variable was smoking behavior (current smoking versus nonsmoking). Odds ratios (ORs) and 95% confidence intervals (CIs) for each psychosocial predictor of the dependent variable were calculated. ORs were reported as a measure of the magnitude of the effect for each variable in the model.

## Results

### Respondents

The sample was composed of 447 self-identified Latina and 160 self-identified non-Latina white adolescents 13-18 years old. A similar proportion of Latinas and non-Latina whites were



13-16 (55%) and 17-19 (45%) years of age. Disposable weekly income was also similar among both ethnic groups. The immigrant status was determined by the answer to the following questions: In what country were you born? How long have you lived in the United States? Where was your father born? Where was your mother born? Of the total Latina sample, 64% were foreign-born (32% from Mexico, 30% from Central America, and 2% from other Latin American countries), 54% had lived more than 10 years in the United States, and of all the Latinas in this sample, 82% had parents who were born in Latin America. Furthermore, 51% of the Latinas scored low in the five-item acculturation scale (31), and 44% answered the questionnaire in Spanish.

Overall, non-Latina white adolescents were more likely to be single (4% versus 18%;  $\chi^2 = 18$ ;  $P < .001$ ), did not have children (6% versus 21%;  $\chi^2 = 20$ ;  $P < .001$ ), were full-time high school students (88% versus 69%;  $\chi^2 = 6$ ;  $P < .01$ ), had a higher (more than \$1000) monthly household family income (91% versus 52%;  $\chi^2 = 75$ ;  $P < .001$ ), and reported better health (79% versus 68%;  $\chi^2 = 6$ ;  $P < .01$ ) than Latina adolescents.

### Demographic Correlates of Smoking Status by Ethnicity

Non-Latina whites were more likely than Latinas to be current smokers (36% versus 15%;  $\chi^2 = 6$ ;  $P < .01$ ) or ex-smokers (79% versus 68%). As Table 1 shows, single adolescents were more likely to be smokers than their married counterparts for non-Latina whites (93% versus 100%;  $\chi^2 = 4$ ;  $P < .05$ ) and Latinas (80% versus 94%;  $\chi^2 = 7$ ;  $P < .01$ ). Full-time school attendance was significantly associated with not smoking for non-Latina adolescents (92% versus 79%;  $\chi^2 = 6$ ;  $P < .01$ ). Among Latinas with a monthly household income higher than \$1000, there was a higher proportion of smokers than nonsmokers (50% versus 64%;  $\chi^2 = 4$ ;  $P < .05$ ).

Latina smokers were more likely to live at home with people who smoked cigarettes than nonsmoking Latinas (59% versus 42%;  $\chi^2 = 7$ ;  $P < .01$ ). Also, Latina adolescent smokers were more likely to live with their parents at home than nonsmoking Latinas (80% versus 68%;  $\chi^2 = 4$ ;  $P < .05$ ). Among Latina adolescents who lived at home, Latina smokers were more likely to have family members who smoked and lived with them (55% versus 40%;  $\chi^2 = 4$ ;  $P < .05$ ). Latina adolescents who reported having children were less likely to be smokers than Latinas who had no children (11% versus 23%;  $\chi^2 = 5$ ;  $P < .05$ ). Non-Latina white adolescent smokers were more likely to report having "poor/fair" health than non-Latina white adolescent nonsmokers (35% versus 14%;  $\chi^2 = 10$ ;  $P < .001$ ).

### Smoking Status and Acculturation

Smoking was significantly associated with higher levels of acculturation toward the U.S. culture in all five measures. Highly acculturated Latinas were more likely to be current smokers (79% versus 68%;  $\chi^2 = 6$ ;  $P < .01$ ) or former smokers (79% versus 68%) than low-acculturated Latinas. Compared with nonsmokers, Latina smokers were more likely to have been born in the United States (58% versus 33%;  $\chi^2 = 15$ ;  $P < .001$ ), to have lived 10 or more years in the United States (74% versus 51%;  $\chi^2 = 13$ ;  $P < .001$ ), to have had at least one U.S.-born parent (35% versus 15%;  $\chi^2 = 17$ ;  $P < .001$ ), to have answered the question-

**Table 1.** Demographic correlates of smoking among Latina and non-Latina white adolescents, 1993\*

Demographic characteristic	Non-Latina white		Latina	
	Nonsmoker (n = 103), %	Smoker (n = 57), %	Nonsmoker (n = 381), %	Smoker (n = 66), %
Age, y				
13-16	64	54	52	48
17-19	36	46	48	42
Marital status				
Single	93	100†	80	94‡
Married/cohabitate	7	0	20	6
Education, y				
≤8	18	19	33	23
≥9	82	81	67	73
Full-time school				
No	8	21‡	32	26
Yes	92	79	68	74
Employed				
No	66	63	77	68
Yes	34	37	23	32
Monthly income				
≤\$1000	7	13	50	37†
≥\$1001	93	87	50	64
Disposable income/wk				
\$0-\$20	58	56	58	59
\$21-\$200	42	44	43	41
Live with parents				
No	11	7	32	20†
Yes	89	93	68	80
Live with a smoker				
No	52	46	58	41‡
Yes	48	54	42	59
Pregnant				
No	91	95	78	86
Yes	9	5	22	14
Have children				
No	92	98	77	89†
Yes	8	2	23	11
Health status				
Poor/fair	14	35§	31	35
Good/excellent	86	65	69	65

\*Percentages may not equal 100% because of rounding of numbers.

† $P < .05$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group..

‡ $P < .01$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group..

§ $P < .001$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group..

naire in English (82% versus 51%;  $\chi^2 = 21$ ;  $P < .001$ ), and to have had a higher acculturation score (71% versus 45%;  $\chi^2 = 16$ ;  $P < .001$ ). There were no significant differences in the proportion of smokers among the two major Latino groups, Mexican and Central American (14% versus 23%;  $\chi^2 = 2$ ;  $P = .18$ ).

### Personal Correlates of Smoking

Latina adolescents reported higher levels of self-efficacy in avoiding smoking (86% versus 71%;  $\chi^2 = 20$ ;  $P < .001$ ), were less likely to report a willingness to smoke even if risky (13% versus 34%;  $\chi^2 = 36$ ;  $P < .001$ ), were far more likely to report spending their free time with their family (56% versus 18%;  $\chi^2 = 71$ ;  $P < .001$ ), had lower emotional distress scores (61% versus 71%;  $\chi^2 = 5$ ;  $P = .05$ ), and were far less likely to report a will-

ingness to take risks (52% versus 89%;  $\chi^2 = 70$ ;  $P < .001$ ) than non-Latina adolescents. Latina adolescent smokers were far more likely to report higher levels of emotional distress (76% versus 58%;  $\chi^2 = 7$ ;  $P = .01$ ) and low self-esteem (59% versus 43%;  $\chi^2 = 6$ ;  $P = .01$ ) than nonsmoking Latinas.

Smokers reported low levels of self-efficacy and a greater willingness to continue smoking even if they knew it was risky than nonsmokers (non-Latina whites: 77% versus 11%,  $\chi^2 = 70$ , and  $P < .001$ ; Latina adolescents: 61% versus 5%,  $\chi^2 = 159$ , and  $P < .001$ ) (Table 2). A higher proportion of smokers, compared with nonsmokers, reported spending their free time with friends or alone rather than with their families in both ethnic groups (non-Latina whites: 95% of smokers versus 76% of non-

smokers,  $\chi^2 = 9$ , and  $P < .01$ ; Latinas: 74% versus 39%,  $\chi^2 = 28$ , and  $P < .001$ ). Willingness to take risks was significantly associated with being a smoker (non-Latina whites: 98% versus 84%,  $\chi^2 = 7$ , and  $P < .01$ ; Latinas: 76% versus 48%,  $\chi^2 = 18$ , and  $P < .001$ ). Smokers in both ethnic groups perceived having more serious problems (non-Latina whites: 58% versus 40%,  $\chi^2 = 5$ , and  $P < .05$ ; Latinas: 38% versus 22%,  $\chi^2 = 8$ , and  $P < .01$ ) and were more likely to approve smoking by significant others compared with nonsmokers.

## Normative Expectations

The psychosocial factor of significant others' smoking approval was significantly associated with smoking status in both ethnic groups. Smokers were more likely to report higher smoking approval from significant others compared with nonsmokers (non-Latina whites: 84% versus 40%,  $\chi^2 = 27$ , and  $P < .001$ ; Latina: 60% versus 33%,  $\chi^2 = 40$ , and  $P < .001$ ). Smoking was associated significantly with peers' alcohol and drug use in both ethnic groups. A higher proportion of smokers than nonsmokers was found among adolescents who had friends who used drugs and alcohol in both the non-Latina white (95% versus 71%;  $\chi^2 = 13$ ;  $P < .001$ ) and the Latina adolescent groups (83% versus 50%;  $\chi^2 = 25$ ;  $P < .001$ ). Non-Latina white adolescents were more likely than their Latina counterparts to have peers who used drugs and alcohol (79% versus 55%;  $\chi^2 = 29$ ;  $P < .001$ ). Latina smokers reported higher social smoking triggers (89% versus 76%;  $\chi^2 = 6$ ;  $P = .01$ ) compared with the nonsmoking Latinas.

## Multivariate Analysis

Three separate multivariate logistic regressions (33) were used to assess psychosocial predictors of smoking status for non-Latina whites, Latinas, and for the entire sample (Table 3). Self-efficacy and intention to smoke were statistically significant predictors of smoking status among adolescents. Overall, compared with nonsmokers, smokers reported low levels of self-efficacy in avoiding smoking, believed that they would continue to smoke even if risky, and reported spending more of their free time with friends or alone.

Latina smokers were more likely to have low self-efficacy in avoiding smoking than were Latina nonsmokers. They were also more likely than nonsmokers to report an intention to smoke even if risky. Latina nonsmokers were more likely to spend their free time with family members than were smokers, who tended to spend their free time with friends or alone. Latina smokers were more likely to perceive higher peer approval of smoking than nonsmokers. For non-Latina whites, self-efficacy, intention to smoke, personal approval of others' smoking, and having serious problems were predictors of smoking.

## Discussion

Personal and normative predictors of smoking status of adolescents across ethnic groups were explored. Results revealed that self-efficacy to avoid smoking, intention to smoke even if risky, perception of peers' smoking approval, usage of free time, and personal approval of others' smoking were significant predictors of smoking status.

**Table 2.** Psychosocial correlates of smoking among Latina and non-Latina white adolescents, 1993\*

Psychosocial factors	Non-Latina white		Latina	
	Nonsmoker (n = 103), %	Smoker (n = 57), %	Nonsmoker (n = 381), %	Smoker (n = 66), %
<b>Personal factors</b>				
Self-efficacy to avoid smoking				
High	6	72†	6	59†
Low	94	28	94	41
Risk taking				
Low	16	2‡	52	24†
High	84	98	48	76
Usage of free time				
With family	24	5‡	62	26†
With friends/alone	76	95	39	74
Self-esteem				
Low	40	54	43	59‡
High	60	46	57	41
Approval of others' smoking				
Low	76	15†	76	37†
High	24	85	24	63
Emotional distress				
Low	30	27	42	24‡
High	70	73	58	76
Intention to smoke				
Low	89	23†	95	39†
High	11	77	5	61
Have serious problems				
Low	60	42§	78	62‡
High	40	58	22	38
<b>Normative expectations</b>				
Significant others' smoking approval				
Low	60	16†	67	41†
High	40	84	33	59
Drug and alcohol use by friends				
Low	29	5†	50	17‡
High	71	95	50	83
Peer's smoking approval				
Low	44	49	47	36
High	56	51	53	64
Social smoking triggers				
Low	26	18	24	11‡
High	74	82	76	89

\*Percentages may not equal 100% because of rounding of numbers.

† $P < .001$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group.

‡ $P < .01$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group.

§ $P < .05$  by  $\chi^2$  comparing smokers and nonsmokers within each ethnic group.



**Table 3.** Multiple logistic regression results for the psychosocial predictors of smoking status by ethnicity

Psychosocial predictor	Non-Latina white adolescent		Latina adolescent		Non-Latina white and Latina adolescents	
	OR	95% CI	OR	95% CI	OR	95% CI
Self-efficacy to avoid smoking						
High*						
Low	11.9	3.1-45.4†	10.8	4.5-25.8†	10.4	5.2-20.9†
Usage of free time						
With family*						
With friends/alone	10.3	0.9-113.2	3.8	1.7-8.7†	3.9	1.9-8.1†
Intention to smoke even if it is risky						
Low*						
High	6.2	1.9-20.6‡	13.1	5.5-31.3†	10.1	5.2-19.7†
Perceived peer's approval of smoking						
Low*						
High	1.2	0.4-3.8	2.7	1.2-6.0‡	2.3	1.2-4.4§
Personal approval of significant others' smoking						
Low*						
High	8.4	2.5-28.2†	1.5	0.7-3.4	2.5	1.3-4.8‡
Have serious problems						
No*						
Yes	4.5	1.3-15.7‡	1.2	0.5-2.7	1.7	0.9-3.3

\*Reference group. The outcome variable is smoking status (0 = nonsmoker; 1 = smoker).

† $P < .001$ .

‡ $P < .01$ .

§ $P < .05$ .

Self-efficacy to avoid smoking and intention to smoke were the strongest predictors of smoking among both ethnic groups. Latina and non-Latina white current smokers may underestimate their ability to quit smoking. In contrast, nonsmokers perceived that they could successfully keep from smoking. The low confidence among female smokers in their ability to quit smoking may be related to their level of perceived nicotine addiction (7,12), exposure to other smokers (34), their perceived approval of smoking from peers, and lack of parental disapproval of smoking (18). Self-efficacy appears to act as a buffer that protects adolescents from peer influence to smoke (35).

In this study, "intention to smoke even if it is risky" was also a strong predictor of smoking across both ethnic groups. Behavioral intentions to smoke have been associated with the onset of smoking in approximately 90% of prospective studies on adolescents (35). In longitudinal studies, intentions to smoke predict subsequent smoking (2). Thus, behavioral intention to smoke is proximal to both the onset and continuation of smoking and is a reliable predictor of future smoking behavior among adolescents.

As reported before (16), we found that spending free time with family was a protective factor in preventing smoking for Latina adolescents. Familism ("familismo") (36), one of the strongest Latino cultural values, may explain why Latina adolescents spent more time with their family and were thus protected from smoking. Latinas have a strong identification and attachment with their families and strong feelings of loyalty, reciprocity, and solidarity among members of the same family. Family support and supervision help prevent smoking. For example, teenagers who never smoked were more likely to confide in a parent, but teenagers who smoked were more likely to go to

a friend if they needed help. Almost twice as many teenagers who smoked were left alone at home without parental or adult supervision compared with teenagers who had never smoked (12,37). Thus, the family orientation of Latinas may protect them from smoking and help them resist peer pressures to smoke.

Adolescent approval of significant others' smoking was a predictor of smoking for non-Latina white adolescents. In our study, there was a high correlation between the adolescent's acceptance of smoking by significant others with the perception that others in turn accept their smoking behavior. This may be explained by the adolescent's internalization of social norms to smoke. Thus, adolescents who approve of smoking may be exposed to role models who smoke and who approve of smoking themselves. Furthermore, our univariate results showed that perceived disapproval of smoking by parents, relatives, or friends was significantly associated with smoking in both ethnic groups. Adolescent smoking has been associated with lack of parental concern for adolescent smoking (38), limited involvement of the adolescent in family decisions (39), and an adolescent's belief that significant others will not care if he or she smokes (40). Because Latino adolescents are exposed more to parental influences, they may be less likely to smoke or initiate smoking.

In this study, believing that their peers would not care if they smoked was a predictor of smoking for Latinas. Several studies have reported the importance of peers' influence among Latino youth. Friends' smoking prevalence has also been positively associated with cigarette smoking during the preceding month (41), onset of smoking (2), smoking status (34), and intention to smoke in the future (34). Furthermore, Latino youth may be more vulnerable to peer pressure because of the strong cultural



value of "simpatía" (42), the need to have pleasant relationships, thereby avoiding confrontations.

Because the importance of familismo might be expected to decrease with acculturation (36), and as Latina youth become more acculturated, peer pressure may be more influential than significant others' disapproval of smoking. Our univariate results showed that more acculturated Latinas were more likely to smoke than less acculturated Latinas, as was also reported in other studies among Latina adults (6,43-45). It might be expected that, as Latina youth acculturate, the need to fit in socially may put them at risk of being pressured to smoke, thereby altering the traditional family norms that prevent them from smoking in the first place. Furthermore, because of the stress of acculturation, immigrant Latina adolescents, who are more vulnerable to change and experimentation, may learn that values important at home are not supported at school (46).

The influence of peers is one of the most influential factors in determining when and how cigarettes are first tried. In this study, believing that smoking among peers happens when partying, drinking alcoholic beverages, and seeing others smoke was associated with smoking. Smoking among Latina immigrants may occur more frequently when they are in the company of peers than when they are alone. In this context, youth also tend to overestimate the proportion of their peers who smoke (47) and exhibit a strong need for acceptance by the group reinforcing the adolescent's smoking behavior. Because of the social pressure for Latinas to become acculturated, immigrants are at higher risk of being influenced to smoke when in the company of their peers.

Adolescent smoking may be covaried with other health-compromising behaviors (48). In our study, having higher levels of serious problems in the last 30 days was a predictor of smoking among non-Latina white adolescents. Adolescents who participate in certain kinds of risk-taking behaviors, e.g., drug use and delinquent behavior, have been identified on the National Health Interview Survey on Teenage Attitudes and Practices (12) as more likely to be smokers.

The results of the present study should be interpreted with some caution. Current tobacco research combines bogus pipeline verification with survey administration. However, no such procedure was employed in this study. Thus, underreporting may have occurred. We surveyed a convenient sample of non-Latina whites and Latinas from three major subgroups (U.S.-born, Mexican, and Central American Latinas), which limits the generalizability of our results, thereby requiring further research with other Latina subgroups. The demographic differences found in our sample of non-Latina white and Latinas are comparable to those of the nationwide data which show that Latino adolescents are more likely than non-Latino white adolescents to be poor, to have lower education, to report poor health, and to have high birth and fertility rates (49). This similarity in demographic differences suggests that the samples are not biased, since no major differences were found between the samples.

Despite the above limitations, this study extends previous knowledge of the personal and social predictors of smoking among Latina and non-Latina white youth. The results also suggest that, independent of their ethnic background, young adolescents need skills to enhance their efficacy at quitting smoking

and to improve their refusal skills in dealing with social situations in which their peers smoke. To reduce the risk of smoking initiation among immigrant adolescents as a means of being socially accepted by their peers, Latina adolescents would benefit from programs that help them cope with the stress of acculturation. Preventive programs need to encourage more parental involvement in youth activities as well as more involvement of the adolescent in family decisions. Since the value of family, familismo, seems to be a protective factor for preventing smoking among Latina youth, programs that encourage better understanding of traditional Latino values should be promoted.

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# Dietary Practices, Alcohol Consumption, and Smoking Behavior: Ethnic, Sex, and Acculturation Differences

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Current knowledge is scarce on Latino dietary practices. This study compared the dietary practices, alcohol consumption, and smoking behavior of Latinos and non-Latino whites in two randomly selected samples. Telephone surveys of adults 35-74 years of age from the Kaiser Permanente Medical Care Program (Latinos = 844; non-Latino whites = 510) and from census tract-based areas (Latinos = 806; non-Latino whites = 436) were conducted in the San Francisco Bay Area. Latino ethnicity was a significant predictor of dietary and alcohol consumption practices in multivariate logistic regression models after adjustment for sex, education, age, employment, health insurance, marital status, county of residence, and self-perceived health status. Compared with non-Latino whites, Latinos were significantly less likely to report eating vegetables and more likely to eat rice, beans, and fried foods and to drink whole milk. Less acculturated Latinos were more likely to eat fruits, rice, beans, meat, and fried foods and to drink whole milk than more acculturated Latinos. Latino men were significantly more likely to be binge drinkers, and Latina women were significantly more likely to abstain from drinking alcohol during the month prior to the interview. As Latina women acculturate to the U.S. mainstream, they report more cigarette smoking and alcohol consumption. Although Latinos reported higher levels of selected high-fiber foods, the low consumption of vegetables, widespread use of saturated fat, and the heavy drinking and smoking among Latino men, which are associated with the level of acculturation, may increase the risk for cancer. Educational messages targeting less acculturated Latinos should focus on maintaining their current healthy dietary practices of eating fruits, rice, and beans and decreasing their fat consumption. For more acculturated Latinos, emphasis should be placed on resuming the traditional diet. [Monogr Natl Cancer Inst 18:73-82, 1995]

Maintaining lower cancer and cardiovascular disease rates in Latino populations may require an understanding of their life-style, which includes both protective and high-risk factors. Our current knowledge about the nutritional status of Latinos living in the United States is limited. We might hypothesize, however,

that the lower incidence of and mortality rates for colorectal cancer among Latinos compared with non-Latino whites (1,2) may be related to the protective factors of their diet, including the greater consumption of fiber (3). On the other hand, Latinos also have unhealthy dietary practices that may put them at risk for colorectal and other cancers. Mexican-Americans consume less linoleic acid and more carbohydrates, saturated fat, and cholesterol (4) and report lower levels of fat avoidance than non-Latino whites (5,6). Furthermore, the widespread use of saturated fats among Latinos in the preparation of foods (7,8), the excessive consumption of alcohol among Latino men (9), and the higher prevalence of cigarette smoking among Latino men (10) may increase their risk for cancer.

Latinos tend to consume more alcohol (9,11,12) and are more likely to be involved in alcohol-related injuries than the general population (13). Heavy drinking is highly prevalent among Mexican-American and Puerto-Rican men (14), which may explain the higher mortality rates resulting from chronic liver disease and cirrhosis observed among Latinos (1).

The acculturation of Latino immigrants in the United States plays an important role in the changing Latino dietary practices, alcohol consumption, and smoking behavior. Fatty food avoidance (8), consuming less fiber (8), alcohol consumption (15), and smoking (16) increase with acculturation. A recent study (17) showed that, in the United States, foreign-born Latinos had better health than the United States-born Latinos, even after adjustment for age, suggesting that the process of immigration selects persons in good health and that, with acculturation, Latinos' health might deteriorate.

We hypothesized that Latino ethnicity is an important predictor of dietary practices, alcohol consumption, and smoking behavior and that adherence to traditional dietary practices may

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See "Notes" section following "References."



change as Latinos become more acculturated to U.S. norms. To further describe and compare the pattern of dietary practices, alcohol consumption, and smoking behavior among Latino adults compared with non-Latino white adults, we conducted two cross-sectional surveys of randomly selected samples with different average levels of access to health care services: the census tract-based sample and the Kaiser Permanente Medical Care Program (KPMCP) sample.

## Methods

### Selection of Census Tract-Based Sample

We used a modified two-stage, Mitofsky–Waksberg, random-digit-dialing telephone method to sample Latinos and non-Latino whites between ages 35 and 74 years (18,19); we used the 183 census tracts (49 in San Francisco County, Calif., and 134 in Alameda County, Calif.) that had 10% or more Latino residents according to 1980 Census data (20). Six city streets were randomly selected to locate telephone prefixes. This procedure identified 92 three-digit prefixes in San Francisco County and 135 in Alameda County. Computer-generated, random, four-digit suffixes were added to generate 1782 seven-digit, random telephone numbers in San Francisco County and 1514 in Alameda County. When a Latino household was identified, the first five digits constituted a primary sampling unit (PSU). As part of this first-stage sampling procedure, 265 five-digit PSUs (11%) (159 in San Francisco County and 106 in Alameda County) were identified out of 2411 working numbers. In the second stage, 99 random, two-digit suffixes were added to the 265 five-digit PSU prefixes.

Of the 14 346 telephone calls that were made, 1242 (8.7%) persons completed interviews, 777 (5.4%) persons refused, 692 (4.8%) subjects were not contacted, 8011 (55.8%) individuals were ineligible by age or race/ethnicity criteria, and 3624 (25.3%) telephone numbers were nonworking. The response rate was 62% (1242 of 2019; interviewed/interviewed plus refusals) among known eligible individuals.

### Selection of KPMCP Sample

The sample was selected from current KPMCP members between 35 and 74 years of age in San Francisco County and Alameda County and identified from KPMCP computer-stored membership files. Because ethnicity was not listed on membership files, the U.S. Bureau of the Census list of Spanish surnames (20) was used to define the sampling frame of potentially eligible Latinos, and then a random sample of 1740 names was selected using a computerized program for a random-number generation. We also selected a random sample of 1133 non-Spanish surnames from the list of age- and county-eligible KPMCP members. Ethnicity was subsequently ascertained by self-identification at the time of the interview.

The telephone call outcome was as follows: (a) *Completed*: 844 (48.5%) self-identified Latinos and 510 (45%) non-Latino whites completed the interview. (b) *Refused*: 91 (5.2%) Spanish-surnamed and 55 (4.9%) non-Spanish-surnamed KPMCP members refused interview. (c) *Not-contacted*: 93 (5.3%) Spanish-surnamed and 103 (9.1%) non-Spanish-surnamed members were not contacted after 10 calls or were sick, dead, or on vacation. (d) *Ineligible*: 712 (40.9%) Spanish-surnamed and 465 (41%) non-Spanish-surnamed members were not eligible because of ethnicity or nonworking telephone numbers. After the ineligible KPMCP members were excluded from the total sample framework because of ethnicity and nonworking telephone numbers, the overall completion rate was 80% (1354 of 1696); the completion rate was 82% (844 of 1028) for Latinos and 76% (510 of 668) for non-Latinos.

### Questionnaire

As part of a larger study to assess knowledge, attitudes, and behavior about cancer and cancer-screening practices of Latinos compared with non-Latino whites in the San Francisco Bay Area (21,22), 11 dietary behavior items selected from the National Health Interview Survey (23) and from a saturated fat/cholesterol avoidance scale (24) were included.

Dietary practice items measured recall of specific foods eaten on the day before the interview. Items included the following: 1) servings of fruit,

vegetables, rice, beans, oatmeal, cereal, and fried foods; 2) type of fat or oil used in cooking; 3) removal of the skin from chicken prior to consumption; 4) frequency of eating red meat, sausage, pork, and eggs; and 5) the amount and type of milk drunk. Saturated fat eaten on the day before the interview was assessed by adapting selected items from the scale developed by Knapp et al. (24). There were five questions on drinking behavior during the previous month: 1) whether any alcoholic beverages were consumed, 2) the number of days alcoholic beverages were consumed, 3) the number of drinks consumed at one sitting, 4) the number of days that five or more drinks were consumed on any one occasion, and 5) the number of times the individual drove while having had too much to drink. Cigarette smoking behavior was assessed by standard questions used by the Centers for Disease Control and Prevention (25).

Demographic items and a previously validated five-item language-related acculturation scale (high acculturation = English speaking; low acculturation = Spanish speaking) (26) were included. The total average was dichotomized into "more" acculturated to the U.S. norm (score of >3) and "less" acculturated to the U.S. norm (score of ≤3). Questionnaire items were developed in Spanish and translated into English using standard double-translation techniques (27). After obtaining verbal consent from the respondents, trained, bilingual interviewers conducted the surveys.

### Data Analysis

Univariate data were presented showing the distribution of responses by ethnicity and sex by use of chi-squared methods. Calculations included the proportion of "yes" responses to each of the questionnaire items by sex within each ethnic group and sample (28,29). Only statistically significant differences between two given proportions at  $P \leq .01$  were highlighted (30).

The effect of ethnicity on nutrition, alcohol consumption, and smoking behaviors was analyzed by use of multivariate logistic regression models (31,32). Separate logistic regressions were performed for each sample, and odds ratios and 95% confidence intervals were reported as a measure of the magnitude of the effect for each variable in the model. Predictor variables included ethnicity (reference group: non-Latino whites), years of formal education (continuous variable), sex (women), age (in years as continuous variable), employment (yes), health care insurance (yes), self-perceived health status (excellent, good), and marital status (married). For multivariate analysis of the Latino sample only, acculturation (reference group: highly acculturated Latinos) was also included as a predictor variable.

## Results

### Sample Characteristics

The KPMCP sample consisted of 844 Latinos and 510 non-Latino whites (Table 1). The Latino group in this sample had an equal proportion of males and females, whereas the non-Latino white group had 41% males and 59% females. The non-Latino whites had more years of education, had a higher income level, and were less likely to be married or cohabitating compared with Latinos. Fifty-eight percent of the Latinos were foreign-born, and 52% scored low on the acculturation index. The census tract-based sample was made up of 806 Latinos and 436 non-Latino whites. Similar to the findings on the KPMCP sample, non-Latino whites had more years of education, had a higher income level, and were less likely to be married or cohabitating compared with Latinos. Sixty-nine percent of the Latinos in the census tract-based sample were foreign-born, and 66% scored low on the acculturation scale (Spanish speaking only).

### Dietary Practices

Table 2 presents the frequency of reported consumption of different types of food and alcoholic beverages as well as smoking behaviors. Items are presented separately by sex and eth-



**Table 1.** Demographic characteristics among Latinos and non-Latino whites, KPMCP and census tract-based samples, San Francisco Bay Area, 1990-1991\*

	KPMCP sample†		Census tract-based sample†	
	Latinos (n = 844), %	Non-Latino whites (n = 510), %	Latinos (n = 806), %	Non-Latino whites (n = 436), %
Total	100	100	100	100
Sex				
Men	51	41‡	49	49
Women	49	59	51	51
Age, y				
35-49	50	50	61	62
50-74	50	50	39	39
Employment				
Full- or part-time	74	73	67	64
Unemployed/retired	26	27	34	36
Education				
High school or less	70	39‡	74	26‡
Some college or more	30	61	26	74
Marital status				
Married, cohabitating	73	65‡	64	51‡
Unmarried	27	35	36	49
Income, U.S. dollars				
<30 000	72	50‡	64	35‡
≥30 000	28	50	36	65
Birthplace				
United States	43	90‡	31	93‡
Mexico	27	0	30	0
Central America	22	0	30	0
Other	9	10	9	7
Acculturation				
Low	52	N/A	66	N/A
High	48	N/A	34	N/A

\*Percentages may not equal 100% because they are rounded data.

†N/A = not applicable.

‡P<.001 by chi-squared comparisons of Latinos and non-Latino whites within KPMCP and census tract-based samples.

nicity for the KPMCP sample and the census tract-based sample.

### Fruit and Vegetable Consumption

A large proportion of respondents from both samples reported eating fruits and vegetables on the previous day. Non-Latino whites reported eating vegetables more frequently than Latinos and reported a higher frequency of eating three or more servings of fruits and vegetables on the previous day. The highest frequency of eating three or more servings of fruits and vegetables on the previous day was reported by non-Latino white women, particularly in the KPMCP sample. The difference in consumption of three or more servings of fruits and vegetables in the previous day was greater in the KPMCP sample than in the census tract-based sample, especially for non-Latino whites.

### Fiber Consumption

The proportion of Latinos eating rice and beans was about double that of non-Latino whites in both samples. Among Latinos, men reported a significantly higher consumption of beans and rice in both samples. A higher proportion of non-Latino whites reported eating oatmeal or cereal than Latinos in both samples. Significantly fewer Latino men reported eating

oatmeal or cereal on the previous day than Latina women in the census tract-based sample.

### Fat Intake

A significantly higher proportion of Latinos reported eating fried food on the day before the interview than non-Latino whites in both samples. Regardless of ethnicity, a significantly higher proportion of men than women reported eating fried food, particularly in the census tract-based sample.

A higher proportion of women reported removing the skin of chicken prior to cooking and eating less red meat (two or more times a week) compared with men, regardless of ethnicity or sample. Men reported eating more sausage, bacon, and pork than women. Latina women reported eating fewer eggs than Latino men in the census tract-based sample.

A significantly higher proportion of Latinos reported drinking whole milk than non-Latino whites in both samples. In addition, a higher proportion of Latinos, especially Latino men, reported drinking more than one glass of milk on the day before the interview than non-Latino whites in both samples.

Ethnicity more than sex was associated with the types of fat used in household cooking. For example, a higher proportion of Latinos reported using lard or vegetable oil for cooking than non-Latino whites in both samples. Olive oil was used sig-

**Table 2.** Frequency of selected nutritional practices, alcohol consumption, and smoking behavior among Latinos and non-Latino whites by sex, San Francisco Bay Area, 1990-1991\*

	KPMCP sample: ethnicity						Census tract-based sample: ethnicity					
	Latino, % "Yes"		Non-Latino whites, % "Yes"		Total, % "Yes"		Latino, % "Yes"		Non-Latino whites, % "Yes"		Total, % "Yes"	
	Women (n = 412)	Men (n = 432)	Women (n = 302)	Men (n = 208)	Latino (n = 843)	Non-Latino white (n = 510)	Women (n = 408)	Men (n = 398)	Women (n = 222)	Men (n = 214)	Latino (n = 806)	Non-Latino white (n = 436)
Nutritional practices												
Percent who ate specific food on previous day												
Fruits	85	85	87	80	85	84	78	75	81	78	76	79
Vegetables	80	84	90	89	82	89†	77	77	90	92	77	91†
≥3 fruits/vegetables	34	30	60	46†	32	54†	24	27	46	36	25	40†
Potatoes	34	42‡	37	38	38	38	36	39	40	42	38	41
Rice	54	63‡	30	30	59	30†	54	59	29	34	57	31†
Beans	43	54‡	27	27	49	27†	43	61†	30	30	52	30†
Oatmeal/cereal	42	44	57	53	43	55†	42	30†	48	48	36	48†
Sausage, bacon	7	11	9	10	9	9	5	11‡	8	16‡	8	12
Pork meat	8	11	6	9	10	8	10	15	9	20†	13	14
Eggs	22	27	18	25	25	21	24	33‡	15	22	28	19†
Whole milk	29	32	15	21	31	17†	46	45	19	29	46	23†
>1 glass of any milk	35	47†	41	35	41	39	43	50	38	39	47	39‡
Red meat >2 times a week	61	59	50	63‡	60	55	57	68†	44	60†	62	52†
Always remove chicken skin	59	45†	57	43‡	52	51	63	46†	61	49‡	55	55
Fried foods	33	41	23	28	37	25†	35	50†	19	31‡	42	25†
Used for cooking												
Lard/meat fat	8	7	3	5	8	4‡	10	15	6	7	13	7†
Butter	19	18	20	18	19	19	38	41	43	39	39	41
Margarine	34	27	37	28	30	33	55	52	53	57	53	55
Vegetable oil	83	84	79	77	83	78	88	90	81	85	89	83†
Olive oil	48	42	62	58	45	60†	50	42	68	60	46	64†
Alcohol consumption												
Liquor past month	42	59†	57	65	51	61†	37	64†	64	71	50	67†
≥5 drinks at one sitting	9	35†	10	18	25	13†	15	47†	9	29†	35	19†
Drink and drive	1	6	1	3	4	2	0	4	2	7	3	5
Smoking behavior												
Current smoker	16	18	17	15	17	16	16	30†	19	24	23	21
Former smoker	20	42†	32	46‡	31	38	17	36†	38	39	27	38†
Never smoked	64	40†	52	39‡	52	47	66	34†	43	37	50	40†

\*Percentages may not equal 100% because they are rounded data.

† $P < .001$  by chi-squared comparisons between sexes or ethnicity.

‡ $P < .01$  by chi-squared comparisons between sexes or ethnicity.

nificantly more often in non-Latino white households than in Latino households in both samples.

### Alcohol Consumption

There were ethnic and sex differences in alcohol consumption. Compared with Latinos, a higher proportion of non-Latino whites reported drinking any alcoholic beverage during the past month in both samples. A significantly lower proportion of Latina women in both samples compared with Latino men reported having consumed any alcoholic beverages in the past month. Binge drinking behavior (defined as five or more drinks in one sitting) was significantly more frequent among men in both samples, particularly among Latino men.

### Cigarette Smoking

The proportion of current cigarette smokers among Latinos and non-Latino whites was similar in both samples. A sig-

nificantly higher proportion of Latino men reported being current smokers than Latina women within the census tract-based sample. A higher proportion of non-Latino whites compared with Latinos reported being former smokers, especially in the census tract-based sample. Men reported a higher frequency of being former smokers than women in both samples. Women, especially Latinas, reported a higher frequency of never having been smokers.

### Effects of Acculturation on Nutrition, Alcohol Consumption, and Smoking Behavior

Table 3 presents the frequency of reported consumption of different types of food and alcoholic beverages and smoking behavior of Latinos separately by acculturation and sex for both samples.

Fruit consumption decreased with acculturation, while within the census tract-based sample, the consumption of vegetables in-



**Table 3.** Frequency of selected nutritional practices, alcohol consumption, and smoking behavior among Latinos by acculturation and sex, San Francisco Bay Area, 1990-1991\*

	KPMCP sample: acculturation						Census tract-based sample: acculturation					
	Low, % "Yes"		High, % "Yes"		Total, % "Yes"		Low, % "Yes"		High, % "Yes"		Total, % "Yes"	
	Women (n = 222)	Men (n = 219)	Women (n = 190)	Men (n = 213)	Low (n = 441)	High (n = 403)	Women (n = 261)	Men (n = 270)	Women (n = 147)	Men (n = 128)	Low (n = 531)	High (n = 275)
Nutritional practices												
Percent who ate specific food on previous day												
Fruits	82	89	87	80	86	83	80	78	74	68	79	71†
Vegetables	79	86	82	83	83	82	74	74	81	83	74	82†
≥3 fruits/vegetables	31	27	38	33	29	35	20	27	30	28	24	29
Potatoes	32	42	36	41	37	39	36	38	35	42	37	39
Rice	60	71†	46	54	66	51‡	59	65	46	46	62	46‡
Beans	46	60†	41	47	53	44†	55	67†	23	47‡	61	34‡
Oatmeal/cereal	40	38	44	50	39	47†	41	25‡	44	41	33	42†
Sausage, bacon	5	9	10	13	7	11	4	11‡	8	10	8	9
Pork meat	7	12	10	9	10	9	8	16†	14	15	12	14
Eggs	22	29	22	26	26	24	23	33	25	34	28	29
Whole milk	38	40	20	23	39	22‡	52	49	32	38	50	35‡
>1 glass of any milk	34	51‡	36	42	42	39	48	52	35	47	50	41†
Red meat >2 times a week	65	62	57	55	64	56	59	72‡	53	60	65	56†
Always remove chicken skin	64	50†	53	40†	57	46†	68	46‡	56	44	57	50
Fried foods	37	44	28	38	41	33	40	52†	27	46‡	46	35†
Used for cooking												
Lard/meat fat	10	11	6	3	10	5‡	11	15	10	15	13	12
Butter	20	19	19	18	20	18	38	40	39	41	39	40
Margarine	34	29	33	25	32	29	57	50	50	55	54	52
Vegetable oil	84	87	81	81	86	81	90	92	86	87	91	87
Olive oil	47	38	49	46	43	47	43	36	62	54	40	58‡
Alcohol consumption												
Liquor past month	38	59‡	46	59†	48	53	29	63‡	51	65†	46	58†
≥5 drinks at one sitting	6	43‡	11	27†	28	21	12	46‡	19	47‡	36	33
Drink and drive	1	4	1	7	3	5	0	2	1	9	1	5
Smoking behavior												
Current smoker	11	16	22	20	13	21‡	11	28‡	26	35	19	30†
Former smoker	15	39‡	25	46‡	27	36‡	17	39‡	17	29‡	29	23†
Never smoked	73	45‡	53	34‡	60	43‡	72	33‡	57	36‡	52	47†

\*Percentages may not equal 100% because they are rounded data.

† $P < .01$  by chi-squared comparisons between sexes or acculturation levels.

‡ $P < .001$  by chi-squared comparisons between sexes or acculturation levels.

creased as Latinos acculturated to the U.S. norm. Less acculturated Latinos reported eating more rice and beans compared with the more acculturated Latinos in both samples. Regardless of the level of acculturation, a significantly higher proportion of Latino men reported eating beans and rice on the previous day compared with Latina women in both samples. Oatmeal or cereal consumption was significantly higher among more acculturated Latinos in both samples.

Less acculturated Latino men reported eating more fried food, such as sausage, bacon, eggs, and red meat, and reported with less frequency removing the skin from chicken before cooking compared with the less acculturated Latina women in the census tract-based sample.

In both samples, a significantly higher proportion of less acculturated Latinos reported drinking whole milk compared with more acculturated Latinos. Less acculturated Latinos also reported eating red meat more frequently than more acculturated Latinos in the census tract-based sample.

A higher proportion of less acculturated Latinos reported using lard or meat fat when cooking than more acculturated Latinos in the KPMCP sample. In contrast, the use of olive oil for cooking was reported by a significantly higher proportion of more acculturated Latinos in the census tract-based sample.

Alcohol consumption during the previous month and cigarette smoking increased as Latina women were acculturated to the U.S. mainstream in both samples. Thus, a higher proportion of more acculturated Latina women reported drinking alcoholic beverages during the month prior to the interview, and more reported being current smokers than less acculturated Latina women. For Latino men, the consumption of any alcoholic beverage during the previous month remained constant with acculturation, except for the more acculturated Latino men in the KPMCP sample, who, compared with less acculturated men, reported a lower frequency of drinking five or more drinks in one sitting. A higher proportion of more acculturated Latinos

reported being current smokers than the less acculturated Latinos in both samples.

## Multivariate Analysis

**Ethnicity.** Latino ethnicity (reference group: non-Latino whites) was a significant predictor of selected dietary and alcohol consumption practices in multivariate logistic regression models after adjusting for sex, education, age, employment, health insurance, marital status, county of residence, and self-perceived health status in the KPMCP and the census tract-based samples (Table 4).

Within the KPMCP sample, Latinos were two times less likely than non-Latino whites to have eaten three or more servings of vegetables and fruits, more than three times more likely than non-Latino whites to have eaten rice, and more than two times more likely than non-Latino whites to have eaten beans on the previous day. Latinos in the KPMCP sample were also more likely than non-Latino whites to have drunk whole milk or to have eaten fried foods and less likely than non-Latino whites to have cooked with olive oil on the day before the interview.

Latinos in the census tract-based sample were more than one and a half times less likely than non-Latino whites to have eaten three or more servings of fruits and vegetables on the previous day. They were almost three times more likely than non-Latino

whites to have eaten rice and approximately one and a half times more likely than non-Latino whites to have consumed beans, eggs, and whole milk, to have drunk more than one glass of milk, and to have eaten fried food on the previous day, as well as to have eaten red meat more than twice a week.

Latinos in both samples were one and a half times less likely than non-Latino whites to have consumed any alcoholic beverage during the previous month. However, Latinos were twice as likely to consume higher quantities of alcohol in one sitting than non-Latino whites in the census tract-based sample. Latinos in both samples were significantly more likely to report never smoking than non-Latino whites.

**Acculturation.** Additional multiple regression models were run among Latinos to identify the contribution of acculturation (reference group: highly acculturated Latinos) to dietary, alcohol consumption, and smoking practices in both samples (Table 5). In the KPMCP sample, less acculturated Latinos were more than three times more likely to eat rice and one and a half times more likely to eat beans than more acculturated Latinos. Less acculturated Latinos were also about one and a half times more likely to drink whole milk, to eat meat more than two times a week, and to remove the skin of chicken prior to cooking it than more acculturated Latinos.

**Table 4.** Odds ratios for Latino ethnicity of selected nutritional practices, alcohol consumption, and smoking behavior

Nutritional practices	KPMCP sample: ethnicity		Census tract-based sample: ethnicity	
	Odds ratio*	95% confidence interval	Odds ratio*	95% confidence interval
Percent who ate specific food on previous day				
Fruits	1.3	0.9-1.9	0.9	0.6-1.3
Vegetables	0.8	0.5-1.1	0.6	0.4-1.0
≥3 fruits/vegetables	0.5	0.4-0.7	0.7	0.5-0.9
Potatoes	0.9	0.7-1.2	1.1	0.9-1.5
Rice	3.1	2.4-4.1	2.8	2.1-3.8
Beans	2.3	1.8-3.0	1.5	1.1-2.0
Oatmeal/cereal	0.8	0.6-1.0	0.9	0.7-1.2
Sausage/bacon	0.9	0.6-1.4	0.7	0.5-1.2
Pork meat	1.2	0.8-1.8	0.8	0.5-1.2
Eggs	1.2	0.9-1.6	1.8	1.3-2.5
Whole milk	1.5	1.1-2.2	1.7	1.2-2.5
>1 glass of any milk	1.0	0.8-1.2	1.3	1.0-1.8
Red meat >2 times a week	1.0	0.8-1.3	1.3	1.0-1.7
Always remove chicken skin	0.9	0.7-1.2	1.0	0.7-1.3
Fried foods	1.4	1.1-1.8	1.8	1.4-2.5
Used for cooking				
Lard/meat fat	1.2	0.7-2.1	1.2	0.7-2.1
Butter	0.8	0.6-1.1	0.9	0.6-1.1
Margarine	0.9	0.7-1.2	0.9	0.7-1.2
Vegetable oil	1.3	0.9-1.8	1.2	0.8-1.8
Olive oil	0.7	0.5-0.9	0.8	0.6-1.1
Alcohol consumption				
Liquor past month	0.6	0.5-0.8	0.6	0.5-0.9
≥5 drinks at one sitting	1.1	0.7-1.8	1.8	1.2-2.8
Drink and drive	1.7	0.5-5.3	1.5	0.6-4.0
Smoking behavior				
Current smoker	1.0	0.7-1.4	1.2	0.9-1.7
Former smoker	0.7	0.6-1.0	0.6	0.4-0.8
Never smoked	1.3	1.0-1.7	1.4	1.0-1.8

\*Odds ratios of Latinos consuming specific food or alcohol and smoking on previous day compared with non-Latino whites (reference group) adjusted for age (continuous), education (continuous), employment (employed = 0; unemployed = 1), county (Alameda = 0; San Francisco = 1), sex (women = 0; men = 1), marital status (married = 0; unmarried = 1), health care insurance (insured = 0; uninsured = 1), and self-perceived health status (good/excellent = 0; fair/poor = 1).



**Table 5.** Odds ratios for acculturation of selected nutritional practices, alcohol consumption, and smoking behaviors among Latinos

Nutritional practices	KPMCP sample: acculturation		Census tract-based sample: acculturation	
	Odds ratio*	95% confidence interval	Odds ratio*	95% confidence interval
Percent who ate specific food on previous day				
Fruits	1.4	0.9-2.1	1.9	1.3-3.0
Vegetables	1.4	0.9-2.2	1.1	0.7-1.8
≥3 fruits/vegetables	0.8	0.6-1.2	1.2	0.8-1.8
Potatoes	0.8	0.6-1.2	1.3	0.9-1.9
Rice	3.1	2.4-4.1	1.9	1.3-2.7
Beans	1.4	1.0-1.9	2.2	1.5-3.2
Oatmeal/cereal	0.9	0.6-1.2	1.0	0.7-1.5
Sausage, bacon	0.6	0.4-1.1	0.8	0.4-1.5
Pork meat	0.8	0.5-1.4	0.6	0.3-1.0
Eggs	1.1	0.8-1.6	0.8	0.5-1.2
Whole milk	1.5	1.1-2.2	1.4	0.9-2.3
>1 glass of any milk	1.1	0.8-1.5	1.5	1.1-2.2
Red meat >2 times a week	1.4	1.0-1.9	1.5	1.0-2.2
Always remove chicken skin	1.5	1.1-1.9	1.4	1.0-2.0
Fried foods	1.2	0.8-1.6	1.2	0.9-1.8
Used for cooking				
Lard/meat fat	1.8	0.9-3.6	0.7	0.4-1.3
Butter	0.9	0.6-1.4	0.9	0.7-1.4
Margarine	1.1	0.8-1.5	1.0	0.7-1.4
Vegetable oil	1.3	0.9-2.0	1.2	0.7-2.0
Olive oil	1.1	0.8-1.5	0.6	0.4-0.9
Alcohol consumption				
Liquor past month	0.7	0.5-0.9	0.7	0.5-1.1
≥5 drinks at one sitting	0.9	0.5-1.7	0.7	0.4-1.3
Drink and drive	0.4	0.1-1.4	0.2	0.0-1.2
Smoking behavior				
Current smoker	0.5	0.3-0.8	0.5	0.3-0.8
Former smoker	0.8	0.6-1.1	1.5	1.0-2.3
Never smoked	1.8	1.3-2.5	1.2	0.8-1.7

\*Odds ratios of low-acculturated Latinos consuming specific food or alcohol and smoking on previous day compared with highly acculturated Latinos (reference group) adjusted for age (continuous), education (continuous), employment (employed = 0; unemployed = 1), county (Alameda = 0; San Francisco = 1), sex (women = 0; men = 1), marital status (married = 0; unmarried = 1), health insurance (insured = 0; uninsured = 1), and self-perceived health status (good/excellent = 0; fair/poor = 1).

In the census tract-based sample, less acculturated Latinos were more than two times more likely to eat fruits, rice, and beans than more acculturated Latinos. Less acculturated Latinos were one and a half times more likely to have drunk more than one glass of milk on the previous day, to have eaten red meat more than twice a week, and to remove the skin from chicken before cooking it than more acculturated Latinos. More acculturated Latinos were one and a half times more likely to use olive oil than less acculturated Latinos.

With acculturation, the likelihood of drinking alcohol and being a current smoker increased. More acculturated Latinos were significantly more likely to have drunk any liquor in the past month and to report being current smokers than less acculturated Latinos.

## Discussion

This study describes the differences in self-reported dietary practices among Latinos and non-Latino whites in the San Francisco Bay Area from a prepaid health care plan as well as from the community at large. Compared with non-Latino whites, Latinos were more likely to consume rice, beans, fried foods, and whole milk on a daily basis, as well as fewer servings of

fruits and vegetables. In addition, Latino men were more likely to be binge drinkers than non-Latino white men, while Latina women were more likely to abstain from alcohol. Within the Latino sample, increased acculturation resulted in dietary habits, cigarette smoking behavior, and alcohol consumption levels resembling those of non-Latino whites.

The lower consumption of vegetables among Latinos compared with non-Latino whites is an observation that confirms findings from other studies that have focused on Mexican-Americans as well as on other Latino subgroups. Data from the California Dietary Practices Survey (33) showed that Latinos of Mexican and Central American origin ate 1.3 vegetable servings per day, while non-Latino whites ate 1.7 servings. Mexican-Americans, compared with blacks and whites, have reported eating fewer carrots and green leafy vegetables while eating more chile, green beans, summer squash, corn, sweet potatoes, lettuce salads, vegetable soups, and dishes containing tomatoes, all of which are sources of vitamin A (3). Shea et al. (34) compared vegetable consumption among Latinos of Caribbean origin, blacks, and non-Latino whites and found that vegetable intake was lowest among Puerto Ricans, Dominicans, and Cubans, intermediate among blacks, and greatest among non-Latino whites. A low intake of all vegetables among elderly

Mexican-Americans was also reported by Bartholomew et al. (35). Thus, low consumption of vegetables is relevant not only for Mexican-Americans, on whom most of the studies have been conducted, but also for other Latino subgroups.

A higher vegetable intake with increased acculturation might be associated with a higher socioeconomic status that provides more acculturated Latinos with more exposure to health education messages in English, to the dietary customs of more frequent vegetable consumption of the non-Latino whites, and to the monetary means for the purchase of vegetables as well as the appliances that can keep them fresh. The lower vegetable intake reported among less acculturated Latinos may also be due to an underestimation in the measurement of vegetable servings. Latinos eat more cooked vegetables (in sauces and soups and with rice) and fewer raw vegetables. Thus, the measure of vegetable servings may not be as accurate in evaluating vegetables eaten in the Latino diet. If Latinos do consume fewer vegetables, it does not seem to be important in the observed lower rate of colorectal cancer among Latinos. Thus, the protective effect of fiber may be derived from the consumption of other foods rich in fiber common in the Latino diet, such as rice, beans, and corn tortillas (8). An epidemiologic study (36) has shown that the protective effect of fiber is more readily seen in populations with higher fat intake, as observed in the Latino diet.

Our survey showed that Latinos and non-Latino whites had a similar number of fruit servings per day. These results differed from the findings of the California Dietary Practices Survey (33), which indicated that Latinos eat more servings of fruits and juices per day (2.6) than non-Latino whites (1.7). It is likely that the difference between that study and our results may be explained by the fact that the California Dietary Practices Survey included juices in the measure of fruit consumption. Drinking fruit juices is a common practice among Mexican-Americans, and juices were found to be the main source of vitamin C in their diet (3). As Latinos acculturate, fruit consumption decreases. This change may be explained by the improvement in socioeconomic status associated with more acculturation. More acculturated Latinos consume less healthy, easier to prepare, and more expensive food alternatives, such as fruit drinks, artificially flavored drinks, and fruit bars.

Our study confirmed that rice and beans are the backbone of the Latino diet as well as the main sources of fiber compared with the diet of non-Latino whites, who reported eating more oatmeal or cereal than Latinos. Legume consumption has been reported to be the main source of dietary fiber for Mexican-Americans by another study (3). This dietary practice is common among other Latino subgroups and may have a protective effect against colorectal cancer. Our data were similar to results from San Diego, indicating that the practice of consuming food rich in fiber decreases with acculturation (8). They were also similar to those from a recent study (37) which confirmed that first-generation Mexican-American women have a healthier nutrient intake than second-generation Mexican-American women.

Among less acculturated Latinos, fiber consumption derived from eating vegetables and cereals is low, but it is high because of the consumption of rice and beans. Reasons for these changes

might be related to changes in lifestyle and socioeconomic status that come with acculturation (e.g., eating more frequently at fast-food restaurants, not having time to cook elaborate dishes at home, and replacing rice, beans, and corn tortillas with chips, cold cuts, and flour tortillas).

Our findings indicate that ethnicity is a major predictor of the consumption of fried foods, eggs, and whole milk. Latinos are more likely to use lard or meat fat when cooking and to eat red meat at least two or three times per week. A previous study (4) has reported greater intake of foods high in cholesterol and saturated fats among Mexican-Americans. These ethnic differences may be explained by knowledge and attitudinal factors as well as by socioeconomic, educational, and cultural factors. When asked which foods one should eat or which beverages one should drink more of to prevent cancer, Latinos were much less likely than non-Latino whites to choose whole grains (38).

Attitudes also have a significant effect on dietary changes. Similar attitudes were found among Latinos and non-Latino whites who had never made any dietary changes for health reasons (38). Income and educational levels had a significant effect on all attitudinal statements; however, the largest effect of both variables was on whether respondents, especially Latinos, thought making changes was expensive.

Our results suggest that the pattern of alcohol use differs between Latinos and non-Latino whites. Although non-Latino whites drank more frequently, Latinos (especially men) drank more during one occasion than non-Latino whites, which is similar to the findings of another study (15). The heavy consumption of alcohol among the less acculturated may be associated with patterns of drinking common in Latin-American countries (39).

Acculturation to the U.S. mainstream had its strongest effect on women, correlating with frequency of drinking and smoking. Highly acculturated Latinas are more likely to be drinkers and to show drinking patterns closer to those of non-Latina white women (40). Highly acculturated Latinas have a higher bicultural affiliation, higher income, more education (41), and a tendency to increase their smoking (42) and drug use (43) as they adapt to the U.S. culture. The process of acculturation provides Latinas with greater expectations of emotional fluidity and social extroversion when drinking (44) as well as an increase in buying power (15) as a consequence of greater labor force participation and career opportunities outside the home (45). Highly acculturated Latinas are exposed to the U.S. mainstream culture, in which the social norms are more accepting of women who drink and smoke and promote more egalitarian behaviors between sexes. Acculturated Latinas should be specifically targeted in alcohol and smoking education and prevention campaigns.

This study has several limitations. First, our data are based on self-reported behavior, which may not be precise. Second, our sample included mainly United States-born Latinos, Mexicans, and Central Americans from the San Francisco Bay Area. These data may not be generalizable to other Latino subgroups or to other parts of the United States. Despite these limitations, the consistency of the results in two different samples and in other studies suggests that the observations are valid.



On the basis of these data and those from other studies, we conclude that dietary recommendations should target Latinos according to their acculturation level. Educational messages targeting the less acculturated Latinos should focus on maintaining their current healthy dietary practices of eating fruit, rice, and beans and decreasing their consumption of fat, especially fried foods, whole milk, and red meat. For the more acculturated Latinos, educational messages should encourage eating fewer prepackaged foods, cold cuts, and fast foods and should encourage resuming the traditional diet of rice and beans. Because one of the main reasons for avoiding dietary changes is enjoyment of what one eats, promotion of alternative methods of cooking among Latinos should focus on taste improvement when baking or broiling.

We confirmed that ethnicity accounted for differences in diet, alcohol consumption, and smoking behavior among Latinos and non-Latino whites. As we hypothesized, acculturation played an important role in diet, alcohol consumption, and smoking behavior. Although Latinos have lower cancer and cardiovascular mortality rates than non-Latino whites, their cancer risk may increase because of the adoption of less healthy dietary practices that seem to come with acculturation. These results need to be considered in developing and implementing behavioral interventions to modify dietary practices, alcohol consumption, and smoking behavior among Latinos.

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## Notes

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# Role of Cigarette Smoking as a Gateway Drug to Alcohol Use in Hispanic Junior High School Students

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**Background:** Many studies have examined predictors of alcohol and other substance use in adolescents, but few have looked specifically at Hispanic adolescents in their junior high school years. **Purpose:** The purpose of this study was to explore the extent to which tobacco use may contribute as a gateway drug for subsequent alcohol use among Hispanic adolescents in San Diego, Calif. **Methods:** A multiple regression procedure was used to test if 7th-grade to 9th-grade change in smoking status predicted 9th-grade alcohol use while controlling for a variety of other variables. **Results:** Among the variables analyzed, increased level of smoking was the strongest predictor of subsequent 9th-grade alcohol use, followed by stronger intentions to drink, female sex, and having grades below a "C." **Conclusion:** 7th- to 9th-grade smoking change is highly predictive of subsequent alcohol use. **Implications:** The study findings suggest that preventive intervention for alcohol use among Hispanic adolescents should focus on changes in smoking status as a significant risk factor and should examine the role of acculturation and other variations that make this population different from other U.S. subgroups. [Monogr Natl Cancer Inst 18:83-86, 1995]

Youth are extremely vulnerable to multiple cancer-causing behaviors. Contemporary lifestyle, limited supportive adult contact, and easy availability of harmful activities or substances present opportunities that are detrimental to the health of the adolescent. Potentially health-damaging behaviors established during adolescence can have lasting negative effects, such as cancer. Tobacco use and alcohol consumption have been identified in Healthy People 2000 as priority areas for the prevention of cancer (2). Tobacco and alcohol use have been estimated to account for 33% of new cancers and cancer deaths in the United States (1). Among Hispanic-Americans, cancer is the second leading cause of death and accounts for approximately 17% of all mortality in this population (2). Excessive tobacco use, the single most important and preventable cause of cancer mortality in the United States, is associated with cancer of the lung, lip, mouth, pharynx, larynx, and esophagus. Excessive alcohol consumption also increases the risk of these cancers, particularly when combined with smoking. Because these substances are known causes of cancer, they offer a major means for its pre-

vention. However, the behaviors related to these substances often begin in adolescence, making youth an important population for primary prevention interventions.

Results of a 1990 survey of California students indicate that 3.2% of adolescents between 12 and 13 years, 7.7% of adolescents between 14 and 15 years, and 17.1% of adolescents between 16 and 17 years smoked cigarettes in the last 30 days (3). In San Diego, Calif., de Moor et al. (4) found rates of tobacco use in 7th (12%)- and 10th (27%)-grade students. Non-Hispanic whites were shown to have the highest prevalence of regular users overall (25.8%), followed by Hispanics (19.7%). Results of the 1993 San Diego County Youth Risk Behavior Survey (5) show that 15.1% of all students (21.3% of whites and 12.1% of Hispanics) in grades 9-12 use tobacco regularly.

Alcohol has become a major public health concern among adolescents as well. Several studies have shown that, among adults, the rates of heavier drinking are higher among Hispanics than among non-Hispanic whites (6). Of particular concern is the fact that alcohol use among adolescent Hispanics is generally found to be similar to or higher than among non-Hispanic whites (7,8). A 1989 survey conducted by the National Institute on Drug Abuse (9) revealed that more than 5 million adolescents (defined as ages 12-17) reported drinking alcohol at least monthly. The San Diego County school-based Youth Risk Behavior Survey shows that 43.7% of all students (56.4% of whites and 43.2% of Hispanics) in grades 9-12 had consumed alcohol at least once in the last 30 days (5). A concern regarding alcohol use among adolescents is that compared with their nonusing peers, adolescents who drink experience other serious problems. Use of alcohol is associated with other drug problems, school failure, unwanted pregnancy, delinquency, human immunodeficiency virus exposure, and other behaviors that threaten health and safety (2).

A great deal of research effort has been devoted to understanding the antecedents of substance abuse among adolescents. Preventing drug use requires identifying factors that predispose youth to substance abuse and then either reducing or eliminating the factors or protecting youth from them. Among Latinos in particular, the factors that have been identified as predictors of

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adolescent drug use include the following: parental/older sibling use (10-12), family disintegration, poverty, poor grades in school (12-15), low self-esteem (12,16), and acculturation (17,18).

A limitation in many studies is that ethnicity is used as a predictor variable and other sociodemographic risk factors that should be considered in a study of substance abuse among adolescents are ignored. As recommended by Schinke et al. (19), "particularly under-researched are relationships between substance use, sociodemographic patterns and behavioral variables among Hispanic youth. Empirical data on these variables and relationships among them would contribute to several areas of research and practice. Knowledge of factors other than ethnic-racial identity that potentially influence substance use among Hispanic youth will aid in identifying populations of at risk youth using other perhaps more salient and concrete variables for predicting substance abuse."

The traditional gateway theories suggest that using one drug leads to initiation of use of stronger drugs (20,21). However, rarely have the three gateway drugs (tobacco, alcohol, and marijuana) been considered separately and their relationship explored. The gateway concept could be applied to the relationship between cigarette use leading to subsequent alcohol use for several reasons. While drinking can proceed without smoking, smoking is almost always followed by drinking. In addition, the mean self-reported age for onset of smoking is lower than that for alcohol onset, suggesting a positive gateway relationship (21).

Successful models for the primary prevention of cigarette use among adolescents have been demonstrated in a variety of Latino populations in a variety of settings (22,23). With the development of effective approaches for preventing (or at least delaying) the onset of cigarette smoking, the possibilities of preventing abuse of other substances may be enhanced. Based on socialpsychologic theories [e.g., Bandura's Social Learning Theory (24) and McGuire's Social Inoculation Theory (25)], previous work has shown moderate success in reducing the rates of onset of regular tobacco use (26-28). These interventions have been less consistent in delaying alcohol use. More needs to be understood regarding the most salient predictors of alcohol use as well as relevant developmental changes.

The purpose of this study was to explore the extent to which tobacco use may contribute as a gateway drug to subsequent alcohol use among Hispanic adolescents. More specifically, changes in smoking status from the 7th to 9th grades were examined as a correlate of 9th-grade alcohol use. Demographics, attitudes, school-related activities, and 7th-grade alcohol use were included as control variables in the investigation because of their documented association with alcohol use.

## Methods

### Participants

Participants were 554 Hispanic middle/junior high school students in San Diego County, Calif., who served as subjects for a study assessing long-term effects of a school-based, tobacco-use prevention program. Elder et al. (29) described the intervention study elsewhere. These students, selected from 22 schools, were examined because they provided data in the 2 years of interest; early in 7th grade (1988) and late in 9th grade (1991). Demographically, the sample consisted of 48% boys and 52% girls. The average age of the sample was 12.33 years at 7th grade.

### Procedures

Participants completed identical, self-report, machine-scannable questionnaires in the 7th and 9th grades that assessed tobacco, alcohol, and other drug use, demographic/background characteristics, and psychosocial factors. These individuals also may have provided questionnaire data later in the 7th and 8th grades, but only the two most distant assessments were considered in this study. Questionnaires were administered in classroom settings under "bogus pipeline" conditions in which saliva samples were obtained to increase validity of self-reports of tobacco (22).

### Measures

**Alcohol use.** Alcohol use was measured in the 7th and 9th grades. In this study, the dependent variable of 9th grade alcohol use and the independent variable of 7th-grade alcohol use were measured by a single indicator response to the question, "How often do you currently use alcohol?" Response options ranged from 1 ("never heard of or never used"), 2 ("tried once or twice"), 3 ("now use about once a year"), 4 ("now use about once a month"), 5 ("now use a few times each month"), 6 ("now use a few times a week"), to 7 ("now use every day or almost every day").

**Changes in smoking status.** Smoking behavior was measured at the 7th and 9th grades. Students rated their current use of tobacco on a scale from 1 (never used) to 7 (now use every day or almost every day). Changes in smoking behavior during that time period were categorized as 0 (if the individual remained a never smoker), 1 (if the individual had decreased smoking), 2 (if the individual was a smoker but did not increase the level of smoking), 3 (if the individual was a smoker who increased the level of smoking), and 4 (if the individual was a nonsmoker who became a smoker). Higher values on the smoking variable indicate increasingly maladaptive behavioral change.

The rationale for the construction of the change in the smoking status scale is based on Healthy People 2000 (2). The end points are directly implied by the priorities for tobacco, namely to "reduce the initiation of cigarette smoking by children and youth" (Goal 3.5). The three middle points are derived from assumptions regarding self-control and addiction, in that a person who is able to cut down on the amount smoked may be more likely to be smoke-free in the future, and a person who increases this quantity is less so. Therefore, the middle points indirectly reflect the second major Healthy People 2000 (2) risk reduction objective, to "reduce cigarette smoking ... prevalence" (Goal 3.4).

**Attitude measures.** Intention to drink alcohol was measured by one item in which participants rated how often they intended to drink alcohol in the near future on a scale ranging from 1 (never) to 4 (a lot). Three scales were constructed to measure assertiveness, self-confidence, and risk and loneliness. The Assertiveness scale was constructed as the mean of three items: "People describe me as a quiet person," "I feel shy around people I don't know," and "It's pretty easy for people to win arguments with me." The Self-confidence scale was constructed as a mean of three items: "I often think about the impression I am making on others," "I am not afraid to speak up," and "I'm a self-confident person." The Risk and Loneliness scale was constructed with a mean of four items: "I often feel that life is not worth living," "I like to do things on the spur of the moment," "I would do almost anything on a dare," and "Emotional support is never available to me." Response ranges for all of these items were from 1 (strongly agree) to 5 (strongly disagree). Higher values on these measures indicated a high level of assertiveness, lower self-confidence, and lower degree of risk and loneliness. The measure of internal consistency (coefficient alpha) for the scales were .49, .50, and .58 for the assertiveness, self-confidence, and risk and loneliness scales, respectively.

**School-related variables.** Students reported grades they usually obtain in school on a binary scale (C and above, below C). Estimates of involvement in school and outside activities, such as school sports and boys' and girls' clubs, also were computed so that higher scores indicated greater involvement. Scores on the activities index ranged from 0 to 7.

**Demographic/background variables.** Several variables measured at the 7th grade were included as potential correlates of 9th-grade alcohol use. Participants' demographic/background factors measured at 7th grade included sex, coded as 1 for male and 2 for female, and mother's and father's education level, ranging from 1 (less than high school) to 4 (college graduate). One questionnaire item used at both the 7th and 9th grades asked with whom the student usually lives and offered the following response options: both parents, a parent and a step-parent, only with mother, only with father, sometimes with mother,



sometimes with father, and other. A two-category living arrangement variable was computed with a 1 designating a two-parent living situation, including a step-parent arrangement, and a 2 denoting any other arrangement.

## Analyses

A multiple regression procedure was used to test if 7th- and 9th-grade change in smoking status predicted 9th-grade alcohol use while controlling for a number of other variables. The variables in the multiple regression were grouped into five blocks or domains: 1) demographics, 2) attitudinal measures, 3) school-related variables, 4) drug use, and 5) changes in smoking status. As described above, there were three to four items or indicators within each block, with the exception of smoking, which included one item. Because we wished to control for all variables, a forced entry procedure of each block was used. Forced entry of all variables will cause many noncontributing variables to be included and will lower the significance of the model. However, the role of each variable is conceptually of interest and thus was included. Because of the correlation among indicators within blocks, the regression analysis usually found that only one to two indicators within a block added significant changes in the multiple correlation coefficient (*R*). Accordingly, simple bivariate correlations (*r*) are also included as a useful method for recognizing the association between any single indicator and the dependent variable.

## Results

Means, standard deviations, and bivariate correlations among all variables are provided in Table 1. Results of the regression analysis (Table 2) indicated that increased level of smoking, stronger intentions to drink alcohol in the near future, being female, having grades below a C, and being more assertive contributed significantly to predicting 9th-grade alcohol use. Change in smoking behavior was the strongest predictor, accounting for 15.5% of the variance alone. Attitude measures contributed an additional 12% and intentions to drink alcohol made a significant individual contribution. Together, predictor variables accounted for 32% of the variance in 9th-grade alcohol use.

## Discussion

The present study examined predictors of alcohol use among Latino adolescents, with a particular emphasis on smoking and changes in smoking status during the junior-high years. Various demographic variables, school-related factors, attitudes, smoking, and drug use were all related to the criterion variable of alcohol use. Among the first two categories, only sex and grades made significant individual contributions to the overall prediction model. Although low grades predicted use, females were, somewhat surprisingly, more likely to drink than males.

Nevertheless, although all categories of variables as blocks contributed significantly to the overall prediction, only attitudes and smoking status made substantive contributions. Obviously, intentions to use alcohol were related to ultimate use. However, individuals who reported being more assertive were more likely to use alcohol than individuals who were less so; this also approached (but did not reach) statistical significance.

Finally, the strongest single predictor of alcohol use was smoking status, with those who had taken up or increased smoking from the 7th to the 9th grade being more likely to use alcohol by the 9th grade.

A shortcoming of the present study was the lack of a specific acculturation variable that may have explained in part 1) why Hispanic females were more likely to drink, and 2) why more assertive and socially comfortable individuals were also more likely to use alcohol. According to Hurtado et al. (28) as well as others (18), the acculturation process may have a negative effect on health behaviors, reversing more traditional expectations (e.g., women being unlikely to engage in antisocial behavior) or mitigating what for the majority population may usually be seen as a salutary and adaptive characteristic (e.g., assertiveness).

**Table 1.** Means and zero-order correlations among 9th-grade alcohol use, smoking status, and other drug use and demographic, attitude, and school-related variables

	Alcohol use, 9th grade	Smoking status	Sex	Living arrangement	Father's education	Mother's education	Intentions	Self-confidence	Self-esteem	Risk taking	Grades	Activities	Alcohol use, 7th grade
Mean	2.43	1.38	1.53	1.16	2.14	2.09	1.44	2.63	3.22	3.78	1.44	12.05	1.48
SD	1.45	1.46	0.49	0.37	1.08	1.04	0.68	0.75	0.91	0.74	0.49	1.35	0.85
Alcohol use, 9th grade	—												
Smoking status	0.51*	—											
Sex	0.09†	0.07	—										
Living arrangement	0.03	0.03	0.10†	—									
Father's education	-0.07	-0.06	-0.13‡	-0.02	—								
Mother's education	-0.05	-0.08	-0.12‡	-0.05	0.49*	—							
Intentions	0.33*	0.15*	-0.02	0.08	0.03	-0.03	—						
Self-confidence	0.07	0.09	0.04	-0.08	-0.14‡	-0.11	-0.02	—					
Self-esteem	0.10†	0.09†	-0.10†	0.01	0.09	0.05	0.08	0.23*	—				
Emotional risk	-0.10†	-0.07	-0.07	-0.12‡	0.06	0.02	-0.23*	0.21*	0.21*	—			
Grades	0.15*	0.10†	-0.07	0.01	-0.14‡	-0.10†	0.01	0.21*	0.04	0.03	—		
Activities	0.12†	0.10†	0.17*	0.02	-0.09	-0.16*	0.14†	0.05	-0.06	-0.02	0.13‡	—	
Alcohol use, 7th grade	0.29*	0.13‡	0.01	0.11‡	-0.04	-0.04	0.65*	-0.06	0.08	-0.18*	0.01	0.121†	—

\**P* < .001 (two-tailed test); minimum number of cases = 400.

†*P* < .05 (two-tailed test); minimum number of cases = 400.

‡*P* < .01 (two-tailed test); minimum number of cases = 400.

**Table 2.** Regression analysis of smoking status predicting 9th-grade alcohol use controlling for demographics, attitudes, activities, and other drug use

	Beta weights (n = 554)
Demographic/background variables	
Sex	0.111*
Living arrangement	-0.005
Father's education	-0.061
Mother's education	0.072
	$R = .153$
	$R^2 = .023$
	Change in $R^2 = .023$
	F value = 2.46†
Attitude measures	
Intentions	0.213‡
Assertiveness	0.072
Self-confidence	0.038
Risk and loneliness	-0.029
	$R = .379$
	$R^2 = .144$
	Change in $R^2 = .121$
	F value = 8.57‡
School-related variables	
Grades	0.119*
Activities	-0.13
	$R = .401$
	$R^2 = .166$
	Change in $R^2 = .022$
	F value = 8.04‡
Other drug use, alcohol use, 7th grade	0.058
	$R = .412$
	$R^2 = .169$
	Change in $R^2 = .003$
	F value = 7.52‡
Change in smoking status	0.399‡
Final model	$R = .566$
	$R^2 = .321$
	Change in $R^2 = .155^*$
	F value = 15.82‡

\* $P < .01$ .

† $P < .05$ .

‡ $P < .001$ .

Another limitation is that measures of the quantity of alcohol consumed were not included in the self-report surveys. Therefore, binge drinking could not be considered separately from light or moderate drinking. Related to this, no differentiation was made between alcohol use versus alcohol abuse. Many researchers believe that any alcohol use among this age group is of concern because of the association of early use with subsequent problems (2,30).

Future studies in this area will definitely want to look at the role of acculturation in predicting alcohol, tobacco, and other substance use. In prediction studies, researchers must attend not only to smoking status but also changes in that status as potential predictors of other maladaptive behaviors. Through such research, appropriate modifications can be made for using prototypical intervention programs for nonmajority adolescents.

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# Latino Male Attitudes and Behaviors on Their Spouses' and Partners' Cancer-Screening Behavior: Focus Group Findings

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The following is a report of the first phase of exploratory research growing out of a parent grant on breast and cervical cancer screening among Latinas in Colorado. This paper reports data gathered from 14 focus groups conducted with Latino (Mexican, Mexican-American, and other Hispanic) males to identify their supportive and nonsupportive attitudes and behaviors toward their spouse's breast and cervical cancer screening. The men represent a cross-section of Latino males, yet the findings presented here are strongly suggestive and not representative of Latinos as a whole. Latinos exhibited three distinct modes of knowledge and attitudes toward their partners' health-seeking efforts. The first mode was characterized by limited knowledge, a lack of information, and for some, disinterest or even disdain. Those in the second mode can be considered "generalists" who knew only generalities concerning their wives' health states and practices. The third mode includes Latino males who were genuinely interested in seeking "meaningful ways" to promote their partners' health and well-being. These long-time married couples seemed to have strong relationships highlighted by a genuine concern for each others' well-being, including their health problems. The younger cohorts were generally unconcerned about their spouses' breast and cervical cancer screening and lacked knowledge in the area. As age and educational level increased, so too did the general awareness and knowledge of breast and cervical cancer increase. Most Latinos, however, lacked specific knowledge about screening, the procedures, or the recommended frequency of such examinations. Most in the community had heard about the topic of breast and cervical cancers through the media (TV, radio, and newspapers). We found that for Latinas, preventive health measures can be greatly enhanced by understanding the husband's knowledge base and attitudes regarding his wife's health and health-seeking efforts. These health-seeking efforts should be understood in light of 1) the husband's own conceptions of health, 2) the husband's knowledge and attitudes about his spouse's conceptions of health and health status, 3) how these change and evolve over the life course and, of course, 4) the husband's knowledge of and attitudes toward his partner's health-seeking practices and behaviors, especially regarding breast and cervical cancer screening. Given the characteristics of each modal type discussed above, a distinct intervention and education strategy would be tailored

for each. By promoting measures of social support regarding breast and cervical cancer screening via the husbands, we could enhance and promote not only womens' health but also begin to approach family health and well-being as a whole. [Monogr Natl Cancer Inst 18:87-93, 1995]

The issue of breast and cervical cancers among women has gained much needed attention over the past 10 years, both in the population at large and in the health-related professions (1-4). Yet, the incidence of these two major diseases among Latinas or Hispanic women has not been well studied or understood (5,6). Data indicate that breast cancer (BC) rates, although lower for Latinas than the general population, are increasing at alarming rates (7,8). More serious is cervical cancer (CC), where the rate for Latinas is about twice that of the general population with attendant problems (9-11).

Because of these data and the serious health issues involved, over time it has become clear that health interventions are needed to increase Latinas' early and regular BC and CC screening (12).<sup>1</sup> As part of a Colorado research project aimed at Latinas overcoming the barriers to BC and CC screening,<sup>2</sup> Latina focus group research found that these women identified important barriers to screening, which included costs of screening, fear of pain or of finding out that one had cancer, lack of knowledge about screening, its efficacy, and other factors, such as lack of transportation and insurance. The women also noted that their spouse's nonsupportive attitudes and behaviors were sometimes powerful barriers to their successful screening behavior.

The researchers followed up this cited barrier to examine, in depth, how this process works between Latinas and Latinos. We did so because, if indeed, Latinos act, at times, as barriers to their spouse's/partner's BC and CC screening, then developing insights into the process by which this occurs is important in mapping out strategies to overcome this particular screening barrier. Ultimately, the knowledge developed could increase

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See "Notes" section following "References."



Latinas' BC and CC screening behavior and quite possibly other related health-seeking behaviors (13-15).<sup>3</sup>

Previous research has shed light on social support and health-seeking processes,<sup>4</sup> yet there are few studies on Latino males or their role and influence on their sexual partner's health-seeking behaviors, especially regarding BC and CC screening. Research on Latino males has, to date, focused on the concept of machismo, masculinity, conjugal decision making, and the like (21-25). Some research on Latino males is found in work on Latino families (26,27). Most of these studies are comparative (28-31) and do not address health-seeking behaviors. There remains a scarcity of research on the roles of Latino men in these families, especially concerning their role in the areas of health, education, employment, and relationships to their children (32).

To investigate Latino males and the extent to which they might be supportive or nonsupportive of their spouses'/partners' BC and CC screening, we developed Latino focus groups to explore a series of sensitive issues related to women's BC and CC screening. We thus began with lay perspectives, concepts, and understandings rather than a physician-dominated perspective or study.<sup>5</sup> Focus group research provided us three advantages. First, we were able to be grounded in the individual's everyday world, subject to the social, cultural, and economic contingencies and demands shaping an individual's health attitudes and behaviors. Second, we were able to explore this uncharted area where no previous research existed.<sup>6</sup> Third, the method allowed us to investigate sensitive topics and the dyadic relationship with the end result of developing sensitizing concepts and understandings to guide our subsequent research.

## Study Context

As discussed above, this research project grew out of a larger 5-year effort focusing on Latinas and their BC and CC screening behavior. This supplemental research project's overall objective is to explore and ascertain the extent to which male nonsupport of Hispanic female partners is a barrier to Latinas' BC and CC screening.<sup>7</sup> In the focus group or first phase of this research, we hope to gain more insight into the process of Latinas' health-seeking behavior, especially as it is affected by their male partners' attitudes and behaviors (34).

We began this research assuming that any effort to begin to educate, intervene, or otherwise enhance Latinas' health-seeking efforts must incorporate an understanding of how their spouses or sexual partners may influence their health-behavior decisions (21), among other important factors not considered in previous research (35).<sup>8</sup> In other words, we are attempting to make sense of Latinos' attitudes, values, and behaviors about health, their knowledge and experience with their partners' health-seeking efforts, and specific health-care screening practices. By health help-seeking practices (36,37) we mean the various methods a person uses or manifests in seeking health care.

## Methods

### Focus Group Sample

Latino males were recruited for the focus groups through advertisements placed in community organization newsletters, mailings, newspapers, and

church bulletins. Second, we sought and secured assistance from community-based leaders and organizations. Moreover, we relied on key community gatekeepers and leaders for entree to the various men's cohorts. Five major organizational and health contacts were established to obtain rural groups.<sup>9</sup> For the urban areas, six major contacts were established in a variety of settings, including health, civic, recreational, and religious sites.<sup>10</sup>

We limited focus group participation to Latinos 18 years of age and older who were married or cohabitating with a Latina who was 18 years of age or older. We drew a broad cross section of Latinos into the focus groups. Respondents represented a wide range of educational, occupational, language preference, age, residential, and acculturation backgrounds. While these groups do not constitute a statistical or representative sample from which scientific generalizations can be made, every effort was made to seek not only a wide variability of subjects on given socioeconomic status (SES) criteria, but also a wide range of possible viewpoints, experiences, and understandings.

Each focus group consisted of males with similar language, age, residency status, and occupational background. The focus groups varied by age (18-29, 30-49, and 50 years and older), language preference (Spanish, English, or both), occupational background (white or blue collar), and location of residence (rural or urban). We made every effort to hold the sessions in the study subjects' respective community at a time convenient for them.

Focus groups varied in size from six men to as many as 14. We developed homogeneous groups so that, for example, a young (18-29 years of age), Spanish-speaking, blue-collar, rural group constituted a group. In this case, the session was conducted in Spanish and later transcribed by a bilingual assistant (38). The key limitation of this exploratory research is the lack of representativeness of the focus groups to the Latino population in general. Yet we sought to generate significant and relevant issues, concepts, and meanings.

### Instrument

The focus group research instrument used in the parent research on Latinas served as a model and guide in developing the men's instrument. The resulting set of questions reflected our objective of ascertaining how men relate to their spouse's health, their knowledge of their spouse's health status and care sought, and, in particular, the men's knowledge of BC and CC screening. We used 13 general questions to guide our Latino focus group sessions. The sessions lasted between 60 and 90 minutes.

### Discussions

The coprincipal investigators led the focus group discussions with support from a research assistant. Both researchers, being bilingual, also conducted the Spanish-language sessions. We first explained to the participants the research project's overall goals, the focus group's purpose, their roles as participants, and those of the researchers. We gained consent from the participants to audiotape the sessions, while reminding them that only their first names would be used during the session and that they would be given \$10 for their participation (\$15 if they drove a longer distance).

We assured the men of the confidentiality of the research data and explained to them how we would guarantee them anonymity. We assured the men that their discussions would be written up, presented in aggregate data format, and that pseudonyms would be used to protect their identity in all reports. All focus group sessions were then audiotaped and later transcribed for analysis.

Our focus group strategy was to discuss first Latinos' perceptions of their own health and then their partner's general health. Next, we examined the men's behavior by asking them how involved they were in their partner's health and health-seeking behavior. We did so to determine the characteristics of supportive versus nonsupportive Hispanic males (38,39). Such questions centered on the knowledge of their spouse's clinic or physician and the type of social support provided or not provided to Latinas' BC and CC screening efforts.<sup>11</sup>

Most important, we were interested in whether there are discernible characteristics, such as traditional versus nontraditional divisions of labor or general or specific sexist attitudes or beliefs, which result in men's interest, concern, and direct involvement in their partner's health versus their disinterest, lack of concern, and noninvolvement. Third, the focus groups addressed the salience of the male's supportive or nonsupportive stance vis-à-vis the partner's health. Of particular interest was whether the men talk to their partners about health and whether they assist her in securing health care, discourage her, and/or place barriers and obstacles to health-care access.



## Findings

**Health conceptions.** We began by asking the men, “What does good health or being healthy mean to you?” We found that the majority of focus group study participants’ conceptions of health were generally symptom centered or defined by disease or illness states across demographic groups or type of focus group. In all of the focus groups, only a few men described a concept of health that was holistic in that it included physical health, mental health, and general wellness. Some participants defined health in terms of the absence or presence of debilitating physical health states, illness, or other chronic states of incapacitation. For both the native and foreign born, as the participant’s age increased, so too did their definition of health expand from one based only on symptoms to one where wellness extended to psychologic dimensions or states.

Interestingly, among younger males, those individuals whose birth family or sexual partner had experienced serious or chronic health problems differed from their age cohorts in their definition of “health.” For these men, the consequence of having experienced serious health problems in the immediate family served to expand and enlarge their definition to include psychologic and/or wellness dimensions similar to their older counterparts.<sup>12</sup>

Among most young males, optimal health was largely defined in terms of the capacity for physical work and recreation as well as the lack of disease or illness symptoms. Older participants, especially those raised in small or rural U.S. and Mexican communities, defined “health” in both physical and mental health terms “...*que uno este bien y sano*—that one is well and mentally sound” or “...*logrando su salud*—maintaining one’s health.”

When we analyzed the responses of focus-group participants according to their age, we saw that the middle-aged cohorts and senior participants increasingly made more references to activities outside the routines of work and familial duties and responsibilities. They also were conversant in the concept of wellness or the maintenance of one’s health. These health-related notions as a group emerged as a more dominant part of these men’s world outlook.

Regardless of low education or occupational status, as age increased or infirmities became more pronounced, participants began to allude to former ideal health states. Herein, they stated their wishes to be free of symptoms, remembering youthful states of resilience that contrasted sharply with their current health states and efforts to maintain one’s health, which included specific conceptions of physical, mental, and/or wellness health states. Not very surprisingly, as SES and level of acculturation increased, so too did the participants’ wellness references. Latinos who had work-related health benefits were more likely to hold conceptions of physical health complementary to mental health, the quality of life, and wellness. Among these individuals, distinct spheres of action and influence (e.g., at church or employment sites) served to provide positive support for these more expanded conceptions of physical health vis-à-vis mental health, quality of life, and wellness.

Among those men 50 years or older from rural backgrounds or raised in Mexico, “spirituality” also emerged as a key theme in their health maintenance and in their recovery from illness. Some men stated that one’s optimal functioning or the regaining of one’s health was accomplished through a return to a sense of spirituality. Such spiritual centeredness was described by general cultural prescriptions and varied according to regional affiliation. Their notion of spirituality included a sense of community and of family life and work that were conducive to a more *balanced* sense of health and well-being.

These men mentioned related issues to how one’s sense of health and well-being is associated with spirituality. These older participants identified gaps in their own knowledge, shortcomings, or a lack of familiarity coupled with an uneasiness with “high-tech” medicine. Another issue this age cohort discussed was unsatisfactory encounters with their physician or clinic. Participants of this age group were attempting to achieve a more balanced life, to gain more holistic or spiritual knowledge, and finally to take action that would make positive change.

For most men in the focus groups, their current state of health was not a primary concern, and even when it was, “it had to be sifted through the competing demands of everyday work, family and friends.” Likewise, a general concern about one’s health was related to “one’s ability to manage the demands versus resources at hand or available.” Only among a few participants were their own or their partner’s health status of such a prime concern that the conduct of their daily life needed to be balanced to address it. Most younger males operated with only minimal importance placed on health or health concerns.

**The female partner’s health concepts.** When we asked the participants about their partner’s definition of health, most men reported that their own conceptions were similar or close to their partner’s conceptions. While the men

reported that their partner’s definition of physical health and/or well-being was extended to mental health considerations, their own definition was less likely to be similarly extended. While few young males’ definitions extended to include mental health, this increased with age. Many men, excluding those approximately under 25, across cohorts reported that their spouse’s health state was strongly influenced by actions of significant others, including their own children, fellow workers, supervisors, and/or the husband himself.

For the younger participants, some health conceptions were bound by stereotypic gender role notions. These notions ranged from distinct non-egalitarian notions to more complementary gender roles. By complementary we mean that men offered to be helpful in ways that were matched, paired, or paralleled to their partner’s needs, requests, or situations.

Other differences in conceptions of health and what influences it surfaced. Of the few men who were supportive of their spouses or were advocates for their partners, the query, “How should men be supportive or involved in their partner’s health?” was a very serious question. They stated that this question should more properly be asked of their partners. As researchers, we felt this response to be both genuine and a way of “modeling” for us about appropriateness, respect, and regard for their “compañeras.”<sup>13</sup> Again, as SES increased, so too did the health references expand beyond simple symptom identification (i.e., health defined as presence or absence of illness) to definitions that included mental health, wellness, and lifestyle considerations. Examples of these are the special needs presented by a second marriage, a diabetic, or someone afflicted with arthritis residing with the family. For more mature participants, especially senior participants, references were made to preventive health and lifestyle issues.

**The meaning of having a healthy partner.** As the group discussions moved to the question “What does having a healthy partner mean to you?”, most participants focused on their spouse’s ability to meet familial, household, and marital roles and responsibilities. The responses of these men were intense, defined, and emotional, and factors such as age and experience with serious health problems entered into the individual’s calculus. For some men, having a healthy partner also meant *a*) providing companionship over the life cycle, *b*) meeting the spouse’s needs first rather than his own or those of the children, *c*) his spouse’s ability to independently do things for herself that accommodate, suit, or please her, *d*) meeting the requirements from his new partner in a new relationship, and *e*) making up for lost opportunities or time.

A smaller number of participants made references to having sought out, wished for, or desired their partner’s fuller participation in daily routines. This desire included participation in the household or at work, with family, greater availability for recreation, and other changes that their current lifestyle, income, or increasing responsibilities had not allowed them to enjoy earlier in their relationship.

For those participants “on their second time around,” that is, in a second marriage (that might include a second family), health concerns were of prime importance. These men faced challenges such as those arising from past marital experiences or health conditions, lifestyle differences, or family history and the psychologic stresses and strains of bringing together or blending two families. Likewise, there was a concern with “doing it right this time” that made health a focal point in daily routines in this new relationship. Some males expressed the need to maintain a more healthy lifestyle in order to keep up with the new spouse or partner.

**Knowledge of their spouse’s/partner’s health-seeking behavior.** When asked about specifics in health-seeking processes, it was clear that the study subjects clearly fell into two groups. Either men were knowledgeable and involved or they had not been and did not expect to be involved. While most participants drew a clear line between their partner’s health-seeking efforts for problems of the family in general and for female health specifically, the participants’ responses were either supportive or nonsupportive and active or passive. They clearly distinguished helping roles in terms of active or passive dimensions (e.g., driving one’s spouse to the doctor was considered passive while helping to set up an appointment was considered an active role). Uninvolved men felt that the consequences, whether short- or long-term, were their partner’s responsibility.

Not surprisingly, seniors who were less educated, less acculturated, and of rural background were less involved and knowledgeable of their partner’s health-seeking efforts. At the same time, it was clear that these seniors held their partner’s responsible for their own health seeking. Furthermore, these participants expected their partner’s to seek needed support from her female family members.

A large number of participants from all cohorts were able to name their partner’s clinic but not necessarily their physician. Most men noted that their



work schedules and the potential for lost income were key factors in assisting their partner in her health seeking. Other obstacles to active participation in their partner's health care included their lack of knowledge about what they should or could do and their feeling "pushed out" or unwanted by the physician or nurse when they had previously attended or assisted their spouse.

Most men reported that their support consisted largely of previsit discussions, driving their partner to the clinic/hospital, waiting with their partner, and discussing and assisting with aftercare or follow-up as it became necessary. Of note was the fact that these men did not participate in these discussions for a variety of reasons, including the confidentiality of the discussions, not wanting to be intrusive in their spouse's affairs, and, of course, respect for their spouse's decision making and actions concerning her health. Only a few men noted that they were drawn directly into the physician-wife discussions. Of the few men who were a part of these discussions, some men initiated them, or their spouses requested their participation, and only occasionally the physician requested their presence.

**Responsibility for contraception.** We also queried: "Who, within the couple, is responsible for contraception?" We examined this area to discern the nature of decision making and responsibility in the dyad. Older, less educated participants from rural backgrounds reported several common limitations with contraceptive use. Generally, it had not been an option during their reproductive years because of religious restrictions, the fact that the pill was then unavailable, and/or there had been a lack of family planning services at that time in low-income and underserved Mexican-American or Latino communities. Most men stated that it was the woman's responsibility, if it was anyone's, or that contraception was discussed only after it had become a health issue, usually after a difficult pregnancy, birth, or miscarriage. Among younger, low SES participants, the issue was more a matter for the male's protection (from sexually transmitted diseases) than it was for the participants' female partner's benefit.

Middle-aged males (30-49 years old) reported that over the course of the marriage, the primary responsibility for contraceptives had changed and shifted from one partner to the other. A good number in this middle-aged men's cohort indicated that they bore the responsibility directly. Some of these men got a vasectomy. These Latinos made this decision with their partner's knowledge, consent, and concurrence and suggested that it was not a difficult decision to reach. They further reported that they had undergone the procedure out of concern/consideration for the spouse's health (i.e., not getting pregnant again given its dire consequences) as well as for economic and quality of family life considerations.

Those who had not sought a vasectomy said that they arrived at their decision on untested assumptions or inferences or because they did not talk about those things with their spouse. Subjects who got vasectomies reported an "openness in their relationship" that allowed for shared discussions, decision making, and actions. The range of knowledge concerning vasectomies, the involvement, and the type of support between spouses was greater among participants who had had a vasectomy than among those who had not.

**Issues related to breast and cervical cancers.** Participants reported three distinct sets of responses regarding their partner's BC and CC practices: *a*) a lack of knowledge and some degree of uncomfortableness or disinterest, *b*) some general unspecified knowledge with some uneasiness, and *c*) some specific knowledge and familiarity about their partner's BC and CC self-examination practices and some ease in discussing their own or their partner's concerns about these practices.

Among younger and older cohorts in the focus groups, the less acculturated, and the more traditionally oriented, we encountered a "minimalist" knowledge and attitude response set. By "minimalist" we mean that the participant's responses were limited, unspecified, and/or noncommitted to our questions on BC and CC and their spouses. Yet as age, SES, and acculturation increased, we found that participants were more likely to report some generalized knowledge that also reflected being more receptive and supportive of their partner's BC and CC self-examination practices.

Among participants who had a relative or a partner with a serious health problem, we found that participants' responses, regardless of SES, age, or acculturation, reflected increasing levels of knowledge, support, and familiarity. Yet, for some men there is a clear sense of disinterest in this topic, while some even displayed disdain. Disdain and disinterest were reflected in their lack of knowledge (often accompanied by facial expressions, withdrawal of dialogue, or refusal to respond) of their partner's general and specific health-seeking efforts and their lack of a role in their partner's health-seeking endeavors. These men

usually stated that it was "their partner's responsibility" or "a female health problem" outside their own sphere of responsibility.

It is clear that most males across focus group cohorts were not knowledgeable, informed, or familiar with their partner's breast and cervical self-examination practices. Most men were uneasy with this health topic and displayed a mild level of discomfort and an apprehensiveness concerning these practices. This was clear since they distanced themselves from the topics and themes that they considered female health problems.

When participants were asked "Who or where do they turn to for information about breast and cervical cancer preventive measures?" or "Who would they turn to for more information about how they could be more helpful and supportive?", most focus group members quickly drew attention to electronic and print media and to their physician or clinic staff members. However, about one third of all focus group members responded that they did not know who or where to turn to for more information or really what to ask about. Surprisingly, a large number of men indicated that they would seek out materials on BC and CC to read, would be willing to speak to a health-care professional, would be willing to seek out a worksite health specialist, or would readily turn to another informed family member or friend. Ironically, many of these respondents were not fully involved with their spouse's health and were not as supportive as one might expect from their previous statements. Almost all agreed that there needed to be a place and way that one could be more informed. A few commented that this matter was not just a question of information or access to information, but one of making the information and health-related processes relevant to their lives and health situations.

Only a few males related that they had attended worksite or health-clinic education workshops or related sessions. Most participants reported not having these forums available and did not know of their availability. While most groups' members were cognizant of existing health-fair activities and recent office visits made by their spouses, very few could speak in depth about the issues addressed at either site. Almost all focus group members believed that their attending physician or clinic could be a key source for BC and CC education materials, but very few men reported having sought out such information.

**Social support in their spouse's/partner's health-seeking behavior.** For those in our focus groups who were rural migrants, knowledge and involvement in their spouse's health-seeking encounters were mitigated or cut short by the males' work responsibilities that usually separated them from their spouses and families. For a few of these rural men, a woman's health problem was best handled by the woman herself, a female sibling, or her mother. Involvement for the man here was only minimal. Yet, these rural males mentioned that they would be supportive as the need arose and that they had encouraged their spouses' health-seeking behaviors. They commented about what they believed were the norms of needing to be supportive of their spouses: "*para cumplir*—to do your part or be responsible" or "*...deshacerse de esa preocupacion pa' otras*—to take care of this worry so as to deal with other pressing priorities."

For others, lack of involvement was attributed to gender role commitments and obligations. Generally, the spouse's mother, mother-in-law, daughter, daughter-in-law, or another close family member was identified as the appropriate person to assist the spouses. Among participants with low levels of acculturation, low SES, and rural background, we encountered fewer references and less involvement in the health-seeking process. Yet, here too, these experiences were mitigated by personal contact with a serious health problem, occupational status, and educational level.

A similar set of limited involvement pertained to the young men whose responses we have labeled minimalist. Previously, we defined minimalist responses as those characterized by limited answers. Here we expand the notion of minimalist. We mean that these youths' limited responses to our questions can be considered a response set. On the issue of the health status of their spouses, these young Latinos had only minimal or no knowledge of their partner's health states, health experiences, or health outcomes. These youths' method of responding or not responding to our questions allowed them to deter further probing, to suggest their noninvolvement or detachment, and to release them from further responsibilities. In short, a minimalist approach was not just a lack of concern with their spouses' or partners' health, but a way for these young men to distance themselves from any role or responsibility for their partners' health and health care.

As SES, occupational status, and educational experience increased, so did the participants' knowledge of their spouses' physician and/or clinic(s). Furthermore, when the spouse or family had experienced some serious illness, had chronic debilitating conditions, or the husband had undergone such an ex-



perience, the references increased and became more detailed about their spouses' health-seeking efforts. These men also mentioned different support roles that arose. Among some males, the nature, type, and duration of support suggests that there might be clear differences in their spouses'/partners' expectation of support. The spouse might expect the male *a*) to not play a part in the health-seeking role, *b*) to minimally just be there, to be a good ear, or to walk with their partner through this troubled episode, *c*) to be much more involved and serve as a coach, a patient advocate, or finally, *d*) to serve as a model of behavior change.

For some males across cohorts, the issue of offering social support was a question of appropriateness *a*) of a male's gender role, *b*) their knowledge of female health problems, *c*) whether a nurse or doctor would permit their involvement (patient confidentiality), *d*) whether the patient (spouse) would permit her husband's involvement (patient confidentiality), and *e*) whether their economic condition would allow for or permit their involvement (patient's household finances).

Finally, rather than the participants' involvement being simply a question of a matter of health condition or just another problem at hand and its resolution for them to handle, participants reported that many treated their involvement as ancillary. More concretely, it was a question of whether the study subjects would be allowed in the health-seeking process by his partner and, just as important, by the nurse, and/or by the attending physician. Their comments exhibited a wide range from: "that it was not a simple matter of addressing what was wrong (with her), but (more) a question of what needs to be done—how I know...", "what (role can I play) am I supposed to do," and "...how does this fit in with competing demands?"

Many men spoke of feelings of being unwanted, ignored, and occasionally asked "what was he doing (being there)..." or being "asked to leave—move to the visitor area."

Those men who reported that their spouse's/partner's expectations coincided with their own emphasized "process" rather than "outcome." They emphasized that it was not clear to them what role they could play and how their limited efforts could contribute to the health-seeking demands at hand. Moreover, in several men's groups, references were made to the import of a male partner's presence and to his assistance in the couple's managing this situation together, sometimes in a "baptism by fire." The latter reference to a "baptism by fire" referred to the men's supportive attitudes being tested in a specific medical situation. Herein, Latinos made references to their own direct involvement and to their support of their spouses and their extant health problems. Participants' attention to process and outcomes with the health problems were manifested by various types of supportive references. These increased with age, SES, and education.

Some men made references to the need for males to consider weighing and coming to terms with their spouses' needs, "space" in the relationship related to health issues, and appropriateness of their role as a health supporter according to the type of health concern. Specific references were made here to the withholding of support so as not to be seen as being invasive, intrusive, or otherwise usurping their partners' ability, independence, or sense of appropriateness. The men's references suggested four types of support: *a*) advocacy and/or problem-solving, *b*) negotiating and process facilitating, *c*) "accompanyist" and passive support,<sup>14</sup> and *d*) providing space to the spouse by request or by inference.<sup>15</sup>

## Summary and Discussion

This exploratory focus group research (40) aimed at identifying men's level of awareness of and involvement in their partner's health care. We also sought to explore the attitudes the men held and the behaviors they exhibited regarding their partners' BC and CC screening. Specifically, we sought to understand men's support or lack of support for their partner's or spouse's health and its implications for improving Latinas' BC and CC screening behaviors.

This study's key findings suggest that for the Latina, preventive health measures can be greatly enhanced by understanding the husband's knowledge base and attitudes regarding his wife's health and health-seeking efforts. These health-seeking efforts should be understood in light of the husband's own conceptions

of health, his knowledge and attitudes about his spouse's conceptions of health and health status, how these change and evolve over the lifecourse, and, of course, his knowledge of and attitudes toward his partner's health-seeking practices and behaviors, especially regarding BC and CC screening.

More specifically, we found that most males' health conceptions are characterized by the presence or absence of illness and disease states. While these conceptions were found to change as Latinos age and experience serious illness and disease states, balanced conceptions of health that include mental and spiritual components do not emerge until his own or his partner's health has been compromised or they face the challenge of maintaining their health to enjoy the social functioning and activities that are age appropriate. Likewise, a second marriage might elicit a call for the implementation of a more healthy lifestyle and concern and care for the spouse's health.

Second, Latinos in these focus groups exhibited three distinct modes of knowledge and attitudes toward their partners' health-seeking efforts. The first mode was characterized by limited knowledge, a lack of information, and, for some, disinterest or even disdain. The young cohorts whom we have termed "minimalists" were certainly representative of this attitude, while older, more culturally traditional participants also were to be found in this category. Among more reluctant Latinos, one finds not only limited knowledge and familiarity but also methods to avoid responsibility or a role for their partners' health status and health care by displaying disdain and disinterest in their partners' health-seeking efforts. The second mode consists of a "generalist." These participants were supportive of their partners' health seeking, but they possessed only limited knowledge or their involvement was nonspecific. They knew only generalities concerning their wives' health states and practices. Again, not only did increasing age, SES, and education increase the likelihood that participants would be more involved and supportive, so too did a personal experience with serious illness and disease.

The third mode includes Latino males who were genuinely interested in seeking meaningful ways to promote their partners' health and well-being. These Latinos were often found in the older cohorts and had been married for more than 20 years. They seemed to have strong relationships highlighted by a genuine concern for each other's well-being, including the health problems that might now be appearing with increasing age. This was also prominent among younger participants who had had a family member or a partner with a serious health problem and among participants who were remarried.

The younger cohorts were generally unconcerned about their spouses' BC and CC screening and lacked knowledge and interest in this area. Many young men were clearly uncomfortable in discussing this issue, and they were much less willing to discuss their responsibility, if any. As age and educational level increased, so too did the general awareness and knowledge of BC and CC screening increase. Most Latinos, however, lacked specific knowledge about screening, the procedures, or the recommended frequency of such examinations. Most participants had heard about the topics of BC and CC through the media (TV, radio, and newspapers).



Those individuals who had established seemingly strong relationships marked by concern and interest in the spouse's health had developed better dialogue and communication. Some got vasectomies. Overall, those in this group have much to teach and share with the younger participants, who lacked interest, concern, and involvement. Given the characteristics of each modal type discussed above, a distinct intervention and educational strategy should be tailored for each. We will be exploring this in our third phase of our research.

By promoting measures of social support regarding BC and CC screening via the husbands, we could enhance and promote not only the women's health but also begin to approach family health and well-being as a whole. The research has also helped to identify elements, such as improving communication techniques or demonstrating to Latino youth why concern with one's partner's health is vital and necessary, which may serve family-strengthening models. One should keep in mind that these findings are tentative and not representative. They need to be examined further. Nonetheless, this new knowledge can serve to encourage others in this important health area of BC and CC screening.

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## Notes

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<sup>3</sup>The need for screening and early intervention among Latinas has led to NCI-funded intervention research projects. These efforts aim to reduce delays in seeking medical attention, to reduce Latinas' risk of breast and cervical cancer by improving diets, reducing smoking, increasing exercise, and other health lifestyle enhancements. Likewise, recent and current interventions (see articles in this volume: Ramirez et al. and Bakemeier et al.) focus on the community-wide educational efforts for the adoption of regular breast self-examinations, medical-professional physical breast examinations, as well as other lifestyle health promotion activities.

<sup>4</sup>While Latinos/as' health seeking efforts are now drawing the attention of the social science and public health research communities, there are few studies providing data about their decisions to use health care services (16-18). Likewise, there are few studies on Latinos/as' use of preventive care services related to a variety of cancers (19,20).



<sup>5</sup>It should be noted that the parent grant to this research is based on a two-track research methodology composed of 1) a professional side (of both M.D.s and nurses) and 2) a Latina population side. The research proceeded with focus groups and surveys conducted with both populations. With this new male research, we are investigating only the population side.

<sup>6</sup>Focus group research is a useful tool in exploring little researched areas, in helping to supplement survey data findings, and in developing rich qualitative information from respondents. See Ramirez et al. (33) who studied the Latino/Hispanic population and cardiovascular disease.

<sup>7</sup>The study's larger aims are threefold: 1) to assess the nature of a) Latinos' perception of their own health and the health care system in general and b) Latino support or nonsupport of their female partners' health-seeking attitudes and behaviors, 2) to assess the strength of the relationship between Latinos' support or nonsupport and Latinas health-seeking behavior, and 3) to assess the relationship between centrality of support and health-seeking behavior in Latinas.

<sup>8</sup>It is important to note that these factors should not be limited to how "patients" actually make their health decisions, including what considerations or constraints they take into account, how they manage relationships with significant others, and how they cope with the "negative reactions" to their illness. A comprehensive study should extend to general and specific conceptions of health and well-being, their relationship to decision making, how these attitudes change over the life course, and, of course, whether preventive care is part of or distinct from other health-seeking behaviors. This study will examine how Latinas' significant others, their spouses, and sexual partners impact on all of these attitudinal factors and how they affect the health-seeking behaviors of Latinos.

<sup>9</sup>The rural contacts included Clinica de la Campesina in Lafayette, OUR in Longmont, the Colorado Parent Coalition in Lafayette, and the Boulder County Health Department offices in both Boulder and Lafayette.

<sup>10</sup>The focus groups were developed from Our Lady of Guadalupe Church, CSUS-Hispanic Staff ad hoc committee, Boulder County Human Services Department, various Hispanic employee associations, and AFCSME Hispanic workers at CU-Boulder and Boulder County, the Colorado Hispanic Institute, the University of Colorado-Denver Hispanic staff, Servicios de la Raza, two Denver area neighborhood recreation centers (one targeting youth/young adults), and two informal groups of senior citizens.

<sup>11</sup>The focus groups were supplemented with unstructured follow-up interviews of particular focus group members. We did so to provide for additional clarification, alternative perspectives, and understandings.

<sup>12</sup>For example, one young man had two people in his family who had chronic health problems. His wife had arthritis and his mother had diabetes.

<sup>13</sup>The term "compañera" refers to the spouse or partner as a companion in a loving and caring partnership of equals. One would maintain open dialogue and communication on all matters with one's *compañera* to maintain and foster a successful relationship.

<sup>14</sup>An accompanyist is one who is interested in his partner's health seeking, but who has a nonspecific sense of the role. Thus, this type of support is best characterized as a presence, indirect and passive.

<sup>15</sup>"Space" here refers to a situation in which participants were knowledgeable and interested in their spouses' health-seeking behaviors, yet recognized and accepted their spouses' capabilities and decision making in providing unfettered room in which to act.

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# Attitudes of Colorado Health Professionals Toward Breast and Cervical Cancer Screening in Hispanic Women

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**Background:** A variety of economic, cultural, and communication barriers appear to be involved in breast and cervical cancer screening among Hispanic women. These barriers include culture-based embarrassment both for mammography and for Pap smears and fear and hopelessness concerning a diagnosis of cancer. Cost and access barriers are shared by low-income women from various ethnic and racial groups, as is a purported lack of physician referral. Hispanic women may have the latter problem enhanced by a language barrier between physicians and patients when the physicians do not speak or understand Spanish. **Purpose:** The goal of this project, conducted by the Cancer Education Division of the University of Colorado Cancer Center, has been to determine the attitudes and practices among health care providers in areas of Colorado with relatively large Hispanic populations (concerning screening mammography, clinical breast examination, breast self-examination, and Pap testing) and to design interventions to address any deficiencies or problems recognized. These studies were coordinated with telephone surveys and focus groups involving Hispanic women, directed by E. Flores in the Department of Sociology of the University of Colorado at Boulder and by C. Chrvala at the Colorado Department of Health. **Methods:** Data were collected from 520 primary care physicians, nurses, and allied health personnel in 11 Colorado counties through focus groups and mailed questionnaires. Responses were analyzed by considering a variety of demographic characteristics of the respondents and by stratifying the associated practices by percent of Hispanic patients. **Results:** The physicians involved in the focus groups and responding to the questionnaires, as well as their associated nurses and other health care personnel, are generally familiar with the breast and cervical cancer-screening guidelines as developed and disseminated by several organizations, including the National Cancer Institute and the American Cancer Society. Major barriers to screening Hispanic women, as perceived by these health care providers, appear to be cost; lack of transportation, child care, and release from work; fear of diagnosis of cancer; patients considering the test unnecessary; discomfort; and embarrassment. The prompt use of colposcopy to evaluate patients whose Pap smears indicated dysplasia appeared less than optimal, especially among internists. **Conclusions:**

Familiarity with guidelines for breast and cervical cancer screening is widespread among Colorado physicians and associated health care personnel, including those with high percentages of Hispanic patients in their practices. Increased continuing education efforts may be indicated concerning the application of colposcopy to the evaluation of women with abnormal Pap smears and concerning the application of computer technology to cancer-screening reminder systems. **Implications:** Educational approaches to primary care professionals may improve the effectiveness of breast and cervical cancer screening, although a variety of other approaches will also be necessary to decrease barriers to screening of Hispanic women. [Monogr Natl Cancer Inst 18:95-100, 1995]

Barriers to breast and cervical cancer screening among Hispanic women in Colorado are being studied in a tripartite project involving the Cancer Center of the University of Colorado, Estevan T. Flores of the Center for Studies of Ethnicity and Race in America of the University of Colorado at Boulder, and Carole A. Chrvala of the Colorado Department of Health. Studies by others (1-5) have indicated that a variety of cultural, economic, and communication barriers are involved. The former include culture-based embarrassment both for mammography (3) and for Pap smears (6,7) and fear and hopelessness concerning a diagnosis of cancer. Cost and access barriers are shared by low-income women from various ethnic and racial groups as is a purported lack of physician referral (1). Hispanic women may have the latter problem enhanced through a language barrier between physicians and patients when the physicians do not speak or understand Spanish.

This study was designed to survey the attitudes and knowledge of health care providers relating to breast and cervi-

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See "Notes" section following "References."



cal cancer screening. The underlying hypothesis was that successful cancer-screening programs depend on these attitudes and skills among professionals as well as on the knowledge and motivation of women in the population to be screened. This report presents information obtained from practicing physicians and associated health care personnel in 11 Colorado counties through the application of focus groups and mailed questionnaires. These findings are being used to plan educational interventions to address any deficiencies or problems recognized in either the provider or lay groups in the study areas. This aspect of the overall study of breast and cervical cancer screening in Hispanic women in Colorado has complemented the other parts of the Colorado study, reported elsewhere (Flores ET, Mata AG: Latino male attitudes and behaviors on their spouses' and partners' cancer-screening behavior: focus group findings. This Monograph).

The specific objectives of the study reported in this publication are: 1) to determine the attitudes and practices concerning screening mammography, clinical breast examination, breast self-examination, and Pap testing among health care providers for Hispanic women; 2) to integrate the data from this study with those from a survey (by Flores and Chvala) of the frequency of current compliance with these screening procedures in the same areas of Colorado; 3) to determine factors that promote, fail to promote, or act as barriers to screening compliance; and 4) to develop, implement, and evaluate a community-based intervention to increase compliance with these screening behaviors among age-eligible Hispanic women in Colorado.

## Methods

### Study Design

This research study deals with breast and cervical cancer screening among Hispanic women in six specified areas of Colorado—three "intervention" areas, each paired with a control area. These areas were selected by reviewing the demographics of the counties of Colorado, including total population, percentage of Hispanic origin, urban-rural distribution, per capita income, major sources of income, levels of education, numbers of active physicians and nurses, and numbers of hospital beds. Also considered were the presence of activities in each county of the Colorado Mammography Advocacy Project and the Cervical Cancer Tracking and Follow-up System of the Cancer Control Program of the Colorado Department of Health. Three pairs of communities were matched and one from each pair was randomly assigned as an intervention group, the other remaining a control group for focus group and questionnaire surveys.

### Focus Groups

Focus groups involving either physicians or nurses were held in three of the eventual intervention areas of Colorado, i.e., in Weld, Denver, and Bent Counties. No focus groups were held in the control areas, in keeping with the overall study design. Participating health care providers were recruited by the two senior investigators and by a local physician in one county. A total of 34 physicians and 20 other health care professionals participated. Each group lasted approximately 1.5 hours, and each was facilitated by a professional focus group leader using a discussion outline developed by the two senior investigators.

### Questionnaires

Two questionnaires were designed to assess the breast and cervical cancer-screening practices of Colorado health care providers: one for physicians and the other for nurses, physician assistants, and allied health personnel. Each had 26 questions, with most questions similar in each questionnaire. There was somewhat more emphasis in the physicians' questionnaire on factors influencing the

physicians to order mammography or perform Pap smears, while the nurses' questionnaire had several questions on patient education materials. Both questionnaires included a series of demographic questions, including sex, race, ability to speak Spanish, age, years in practice, specialty, practice setting, size and location of the community, and percentage of Hispanic patients in the practice. The physicians' questionnaire was tested on a group of approximately 100 family practitioners during a series of revisions, while the nurses' questionnaire was tested on a group of approximately 20 university faculty and hospital and office staff nurses in the Denver area.

The questions relevant to cervical cancer screening included the timing of Pap smears, the degree and timing of further evaluation following the detection of various abnormalities in Pap smears, factors influencing the decision to perform a Pap smear, presumed barriers to patient compliance, and types of patient and physician reminder systems employed. The questions relevant to breast screening included one asking at what intervals screening mammography would be recommended for patients at varying ages, with and without a positive family history of breast cancer, factors influencing the ordering of mammograms, estimated patient compliance and reasons for noncompliance, attitudes about the effects of screening on cancer patient survival, recent experiences with abnormal tests, and types of reminder systems employed. An open-ended question sought to reveal "any problems of cancer screening particularly associated with your patients of Hispanic origin."

A list of physicians to whom the physicians' questionnaire was mailed was developed with the assistance of the Colorado Medical Society. Mailing lists were available to the investigators only through that source, and it was recognized that, since membership in the society is not compulsory, the lists may not have included all physicians in the regions of interest. The questionnaire mailing lists included physicians in the following Colorado counties only: Larimer, Weld, Denver, Otero, Bent, Prowers, Pueblo, El Paso, Alamosa, Costilla, and Los Animas. Specialties included were family practice, internal medicine, obstetrics/gynecology, and general surgery. Six hundred sixty-two physicians' questionnaires were sent out with a self-addressed, stamped return envelope. A second mailing was sent after 2 months.

The questionnaire for nurses, physician assistants, and allied health personnel was distributed concurrently by including nurses' questionnaires with each physicians' questionnaire. Questionnaires from a given practice were returned in the same envelope so responses from physicians could be correlated with responses from their own personnel.

Statistical analyses employed standard applications of the Student's *t* test and the chi-square test (8).

## Results

Observations were based on the results of focus groups made up of health care professionals and on the responses to questionnaires by physicians and by associated nurses, physician assistants, and allied health personnel.

### Focus Group Results

The observations of three physician focus groups and three nurse/other health care personnel focus groups indicated that health care providers attempted to follow guidelines for recommending and performing breast and cervical cancer screening; however, there are multiple, differing guidelines that contributed added complexity to the situation. All participating health care personnel recognized some degree of responsibility for educating patients about screening. They recognized that two effective motivating factors for women for compliance with screening guidelines are a family history of cancer and a requirement for having a Pap smear prior to birth control prescription renewal.

Barriers perceived by providers to patient compliance with screening recommendations among Hispanic women in particular are shown in Table 1 with suggested approaches to overcoming them.



**Table 1.** Barriers to screening compliance by Hispanic women: professional focus group results

Barrier	Recommendation
Cost of procedures	Health fairs with volunteers
Cost of lost work time	Work-site screening events
Lack of child care	Screening-associated child care
Lack of transportation	Screening in Hispanic communities
Lack of health education	Seminars in women's groups, churches
Language barriers	
Spoken language	Provider language training; use of Spanish-speaking media
Written language	Screening literature brief, illustrated, written at elementary school level
Cultural issues	
Modesty	Provider sensitivity training
Male dominance	Provider sensitivity training
Religious faith	Provider sensitivity training
Women's issues	
Low self-esteem	Provider sensitivity training
Importance of women's health	Patient education
Long waiting times	Efficient scheduling: dedicated sites, times

## Questionnaire Responses

The total number of completed and returned physicians' questionnaires was 268 of the 662 sent out, for a response rate of 41%. Of the nurses' questionnaires accompanying the physicians' questionnaires, 199 were returned, and 198 were suitable for data analysis. The total number of health care personnel associated with the 662 physicians was not known, but if one per physician is assumed, the response rate was 30%. These response rates were lower than desired, and the estimates derived from them involved a degree of uncertainty, limiting their generalizability. For that reason, the characteristics of the respondents were carefully analyzed to assess the representation of the various primary care providers.

**Physician respondent characteristics.** The 268 respondents to the physicians' questionnaire were 81% male and 91% white, and 45% of the total identified themselves as family practitioners, 5% as general practitioners, 22% as obstetrician/gynecologists, 21% as internists, 1% as general surgeons,

and 6% other. The response rates for each group were as follows: family practice, 49%; general practice, 49%; obstetrics/gynecology, 53%; internal medicine, 29%; and general surgery, 62%. Six percent stated they were of Hispanic origin, and 26% stated they spoke Spanish. The median percentages of Hispanic patients in their practices was 15% (range, 0%-98%). The respondents were stratified for certain analyses into four groups based on the percentage of Hispanic patients for those that answered that question, i.e., less than 5% (n = 63); 5%-15% (n = 71); 16%-35% (n = 61); and greater than 35% (n = 64). The distribution of physicians into those four groups corresponded reasonably closely to the percentage of physicians in each group who speak Spanish (12.9%; 26.8%; 22.9%; and 40.6%, respectively). The group of respondents who indicated that over 35% of their patients were Hispanic can be further characterized as 48% in their fifth decade of life; 44% having been in practice between 15 and 24 years; 58% being family practitioners; and 55% practicing in communities of more than 100 000 population (30% were in communities with <25 000 population).

**Mammography.** Analysis of the entire group of physician respondents is presented in Table 2 with respect to answers to the question "At what intervals do you recommend screening mammography for asymptomatic patients in the following age groups, keeping in mind the family history for each group?" For women over age 50, whether or not they have a positive family history of breast cancer, over 90% of respondents indicated that they recommend at least annual mammography. These questionnaires were distributed before the announcement was made by the National Cancer Institute that evidence did not support the recommendation of screening mammography before age 50. Responses concerning women between the ages of 40 and 49 were generally consistent with the recommended screening guidelines at that time (1992), with 88% favoring annual or more frequent mammography for women with a positive family history and 66% favoring mammography at longer intervals for those without a positive family history (plus 30% favoring annual mammography in the latter group). Those favoring annual mammography tended to be older physicians (in practice 25 or more years) rather than younger, family practitioners and internists rather than obstetrician/gynecologists, and from com-

**Table 2.** Physician-recommended interval for mammography: asymptomatic patients\*

Age, y	Family history	<1 y, %	1 y, %	>1 y, %	Request or $\times$ 1, %	Never, %
18-34	+	1	19	26	48	6
35-39	+	3	57	23	17	0
40-49	+	5	83	11	1	0
40-49	-	0	30	66	4	0
>50	+	7	92	1	0	0
>50	-	1	92	6	1	0
40-49	+					
% Hispanic patients in the practice	<5 (n = 61)	5.0†	86.9‡	8.2§		
	5-15 (n = 67)	4.5	89.5	6.0		
	16-35 (n = 60)	8.3	80.0	11.7		
	>35 (n = 63)	4.8	73.0	22.2		

No. of respondents = 268

\*Source: Physicians' Questionnaire, q.10, 14a.

†% exceeding 1992 screening guidelines (more often than annually).

‡% adhering to 1992 screening guidelines (annual mammogram).

§% not meeting 1992 screening guidelines (less often than annually).

munities of over 100 000 population. Compliance with the screening guidelines proposed at that time by the American Cancer Society and the National Cancer Institute was implied by 87%-99% of respondents for all patient age and family history categories except for women between ages 35 and 39 with a positive family history. For that group, 60% of respondents favored annual mammography.

When the responses to this question were analyzed according to the percentage of Hispanic patients in each practice, the results were as shown in Table 2. No question was worded to ask about screening practices specific for Hispanic women in contrast to non-Hispanic women. The result of stratifying the respondents by percentage of Hispanic patients, therefore, only suggests screening approaches likely to affect relatively major groups of Hispanic women. Table 2 suggests that for those respondents with 35% or fewer of their patients being Hispanic, from 88% to 94% favored annual mammography (or more frequent) for women aged 40-49 with a positive family history. However, for the group of 63 respondents who reported having over 35% of their patients being Hispanic, the percentage favoring annual or more frequent mammography was only 77.8%. Whether this reflects a realistic adjustment by these physicians to the financial, cultural, and other barriers to breast screening among Hispanic women is not possible to state from these data. This group of physicians favored annual or more frequent mammography for women over age 50, either with a positive family history (98%) or a negative family history (95%). Responses to the questionnaire for nurses and allied health care personnel also indicate that virtually all respondents favored annual mammography for the group of women aged 40-49 with a positive family history. The reader is again reminded of possible limitations in generalizing these observations to a broader population of physicians and nurses.

**Pap smears.** Eighty-seven percent of physician respondents felt that annual Pap smears should be recommended after the onset of sexual activity. One half stated that the interval should never be extended beyond 1 year thereafter, while one third of respondents indicated that the interval could be lengthened after three annual negative smears. Analysis of the entire group of physician respondents is presented in Table 3 in respect to answers to the question "Following a Pap smear with the indi-

cated abnormalities, at what interval do you recommend further evaluation?" (The abnormalities included atypical squamous cells, cellular changes associated with papillomavirus, mild dysplasia, severe dysplasia, and atypical cells after hysterectomy; suggested intervals from which to choose included either prompt colposcopy or evaluation after 3 months, 6 months, or 1 year.) Only 54% of respondents recommended prompt colposcopy, which is widely advocated as follow-up for minimally abnormal Pap smears. If a 3-month interval with repeat evaluation is acceptable (and this assumes full compliance by the patients), then another 29% of the respondents fell within that guideline.

When the responses to this question were analyzed according to the percentage of Hispanic patients in each practice, the results were as shown in Table 3. Although none of the physician groups exceeded 63% in favoring prompt colposcopy, there was a trend toward increasing use of that technique paralleling the increased percentage of Hispanic patients. (The response rates were not statistically significantly different.) For severe dysplasia, the overall response rate favoring prompt colposcopy was 80%, with the three physician groups with practices exceeding 5% Hispanic patients all indicating over 76%, while 66% of the group with less than 5% Hispanic patients chose prompt colposcopy for severe dysplasia.

The relation of favoring prompt colposcopy to the specialty of the respondent is also shown in Table 3. The specialty group with the highest response rate favoring colposcopy for mild dysplasia was the obstetrician/gynecologists, 78% of whom recommended colposcopy without delay. Of the family practitioners (many of whom are known to perform colposcopy themselves), 54.6% recommended colposcopy; while of the internists, only 25.4% recommended referral for colposcopy. For severe dysplasia, these differences became smaller, with 83% of both obstetrician/gynecologists and family practitioners favoring prompt colposcopy but only 56% of internists recommending prompt referral for colposcopy.

**Nurses, physician assistants, and allied health personnel characteristics.** The 198 respondents whose questionnaires were analyzable were primarily female (94.4%) and white (90.3%). Sixty-two percent were registered nurses, 21.8% were physician assistants, 6.6% were licensed practical nurses, and the remainder were certified or noncertified nursing assistants.

Table 3. Pap smear follow-up\*

Diagnosis	3 mo, %	6 mo, %	Annual, %	Colposcopy, %
Atypical	53	32	7	8
Mild dysplasia	29	15	2	54
Severe dysplasia	18	1	1	80
NI; hx dysplasia	22	53	18	7
Mild dysplasia				
% Hispanic	<5 (n = 60)	51.7		48.3
patients	5-15 (n = 68)	47.1		52.9
in the	16-35 (n = 59)	37.7		55.9
practice	>35 (n = 61)	45.2		62.3
Specialty				
Family practice (n = 97)		40.2		54.6
Obstetrics/gynecology (n = 59)		18.6		78.0
Internal medicine (n = 55)		70.9		25.4
No. of respondents = 268				

\*Source: Physicians' Questionnaire, q. 12d.



Almost 13% stated they were of Hispanic descent, and 19% said they spoke Spanish. It is again pointed out that the responses of these health care providers represented only 30% of the practices surveyed.

**Mammography.** Analysis of the entire group of nurses and associates with respect to answers to the question "At what interval do you recommend screening mammography for asymptomatic patients in the following age groups, keeping in mind the family history for each group?" resulted in similar observations as with physicians (Table 2). No consistent relationship was noted between percentage of Hispanic patients in their associated practices and percentage of health care personnel recommending mammography greater than or equal to the guidelines.

**Pap smears.** Ninety-one percent of nurses and associates responding to the questionnaire felt that annual Pap smears should be recommended after the onset of sexual activity. Analysis of the entire group of nurses and associates in respect to answers to the question "At what interval do you recommend further evaluation of a woman with a Pap smear with dysplasia?" revealed that 51% indicated that colposcopy should be recommended. The data indicate that there is no consistent relationship between percentage of Hispanic patients and type of work-up recommended relative to the guidelines.

**Educational practices and materials.** Questions on the questionnaire for nurses and associates relevant to patient educational practices and materials included type of educational services provided, when these materials were provided, reasons for not providing educational services, and information about educational materials available or provided in Spanish. Eighty percent of respondents said they provided educational materials about Pap smears, 92% said they provided educational materials about breast self-examination, and 88% said they provided educational materials about mammography. The majority of materials are brochures, pamphlets, or fact sheets; however, some practices provide materials on videotape or audiotape. Thirty-one percent stated they provide materials at all visits. An additional 45% provide educational materials only at scheduled, routine visits. Those who did not provide materials cited lack of available, accurate materials as the most common reason. Spanish language materials were provided to Hispanic clients by 58% of respondents. Those not providing them stated they were unavailable or were felt to be difficult to read and not always culturally competent. Of interest were the findings that respondents who worked in neighborhood health centers were twice as likely to provide Spanish language cancer prevention and early detection materials as those in solo or other private practices.

**Effectiveness of screening tests.** Both questionnaires asked the question "To what degree do you believe that cancer survival is significantly improved through early detection with screening tests?" Both physicians and nurses plus associates as groups rated all specified screening tests as improving survival. Each of the four screening tests indicated were rated on a scale of 1 (cancer survival not at all improved) to 7 (cancer survival improved a great deal). The subset of physicians (n = 63) reporting more than 35% Hispanic patients in their practices appeared to be significantly less convinced than associated nurses and other providers that clinical breast examination and breast self-examination, and perhaps even mammography, contributed to

improved survival. Definitive evidence for a decrease in breast cancer mortality through the clinical and self-examinations has not appeared, perhaps contributing to this uncertainty.

**Barriers to effective cancer screening.** Both questionnaires asked "What are the most likely reasons for your patients not keeping an appointment for Pap smears and screening mammograms? Please check all (in the following list) that apply." The results are shown in Table 4. They confirm and extend information obtained from the focus groups previously mentioned. Nurses from practices with more than 35% Hispanic patients were more impressed with the importance of transportation, work releases, and child care than were nurses from other practices and physician respondents in general.

Responses to questions directed at the topic of patient reminder systems in the questionnaires revealed a predominant reliance on chart notes and verbal reminders during office visits. Very little use of computerized reminders, chart stickers, or special cancer screening forms was reported. An intermediate level of use of card files was reported. There was little reported variation in these reminder methods among the four groups stratified by percentage of Hispanic patients.

## Discussion

The professional education portion of this tripartite study of breast and cervical cancer screening of Hispanic women in Colorado has been designed to illuminate areas in the attitudes and behavior of the health care professionals in the six geographic areas of Colorado under study that may benefit from additional emphasis in continuing education activities. Data from other portions of the study are encouraging, in that 67% of Latinas age 50 or older statewide reported having a mammogram within the last year, according to the baseline telephone survey conducted by Flores and associates (unpublished data). Concerning cervical screening, over 95% of Latinas age 25 and older in each of the regions surveyed reported having had a Pap smear in the past, with most (66%) having had the test within the last year.

The data from the telephone survey of Latinas appear to be consistent with the observations from the physician and nurse focus groups and questionnaire surveys reported above, indicating that the Colorado health care professionals surveyed were

**Table 4.** Reasons for failure of patient compliance in screening mammography and Pap smears\*,†

	Physicians	
	Mammogram, %	Pap smear, %
Cost	85.9	61.7
Fear of cancer diagnosis	62.3	51.4
Test "unnecessary"	60.1	54.0
Patient discomfort	54.2	31.3
Patient embarrassment	32.9	51.0
No transportation	25.8	23.4
No work release	24.6	25.8
Patient uninformed	14.5	10.4
No child care	13.3	16.9

\*% of respondents indicating each item as a likely reason.

†Source: Physicians' Questionnaire q. 23, Nurses' Questionnaire q. 23.



familiar with screening guidelines and that, in general, they were in agreement with them. Translation of that knowledge into everyday standard practice is more difficult to assess, but the results of the telephone survey of Latinos suggest an encouraging degree of success. However, potential problem areas have come to light, and these are being explored. Some of these problems were apparent to physicians and nurses who participated in the focus groups, leading to a list of barriers to screening and possible solutions as described in the "Results" section. Their concerns were generally well corroborated in the responses to the questionnaires.

Concerning mammography guidelines, almost all physicians and nurses questioned indicated agreement with annual mammography for women over age 50. The currently controversial group aged 40-49 raised some disagreement, with almost 90% favoring annual (or more frequent) mammograms for those with positive family histories. It was noted, however, that of those physicians with more than 35% Hispanics in their practices, there were only about three quarters who recommended annual (or more frequent) mammograms.

The high risk of cervical cancer in Hispanic women and its tendency to present in relatively advanced stages (9) should underline the importance of continually improving cervical cancer screening programs among these women. The observation was made from the responses to the physicians' questionnaire that colposcopy may not be employed as often or as early as desirable for thorough evaluation of Pap smears indicating dysplasia. Only 54% of physician respondents recommended prompt colposcopy for mild dysplasia (Table 3). Internists seemed particularly reticent to refer patients promptly for this procedure. Differences of opinion exist concerning appropriate follow-up of minimally abnormal Pap smears, although colposcopic evaluation is widely advocated because of the frequency of high-grade disease on biopsy (10). The increase in expense resulting from colposcopy makes the cost barrier noted above even more apparent. However, particularly for those Hispanic women in the mobile seasonal agricultural labor force in Colorado, follow-up Pap smears may be difficult to assure, making prompt colposcopy a reasonable approach to planning appropriate management. It is important that primary care physicians be aware of recent advances in the diagnosis and management of noninvasive cervical carcinoma. Three major presentations of this topic in Colorado, with workshops involving colposcopes, have been made available to large groups of primary care physicians during the past year through the University of Colorado School of Medicine Office of Continuing Medical Education.

Responses to the nurses' questionnaire indicated that the practices with which the nurses are associated provide a high level of educational support for women, with over 90% providing English-language materials on screening. However, only 58% reported Spanish-language materials being available for Hispanic patients. Multiple organizations, including the National Cancer Institute and the American Cancer Society, provide educational materials at no or low cost to lay persons and health care providers, including Spanish-language versions. Information about these resources may need to be more broadly disseminated to fully acquaint health care providers with these materials.

The barriers to breast and cervical cancer screening that were explored during the focus groups and confirmed through the questionnaires present formidable problems to those seeking to increase the rates of screening among Hispanic women. The problem of cost is being partially addressed through federal supplements that support mammography for low-income women. But cost, particularly of mammography, still remains a deterrent for higher-income women without appropriate health insurance coverage. Other associated economic problems, including transportation and child care, are also important. Community groups are approaching the educational needs of Hispanic women in the Colorado study, and health care professionals should assume their responsibility for contributing to these public education programs. In light of the cultural barriers identified, physicians and their associates should seek high levels of cultural sensitivity and competence in their practices, with adequate Spanish-language support, to enhance patient compliance with cancer prevention and screening recommendations. Furthermore, health professionals should strive to improve their screening test reminder systems for themselves and their patients, taking advantage of recent advances in computer technology (11-13). This area also provides a challenge for improved continuing education programs.

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# Social Theory, Social Action, and Intervention Research: Implications for Cancer Prevention Among Latinos

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The aim of this article is to critique and offer a guide to social science and health research that attempts to effectuate healthy changes in the Latino/Hispanic<sup>1</sup> population in the United States. In this article, we discuss and analyze 1) issues of social theory and 2) social action research or intervention models as applied to the Latino experience. Finally, we explore the context of cancer prevention research for Latinos and present a basic conceptual framework from which to address health intervention research with Latinos.

## Theoretical Issues

First, we emphasize the importance of theory and offer a research framework consistent with a dialectical flow between theory, which provides for a testing of (a) the major relationships (hypotheses) and (b) a strategy for social change or intervention and the research findings and conclusions. We also emphasize that theory useful and relevant for developing interventions with Latinos should be contextually grounded in society and should include the following three major factors: 1) racial/ethnic background, 2) socioeconomic status (i.e., class), and 3) gender.

Issues of culture, language, racism, discrimination, and stereotypes are realities of the Latino experience and need to be incorporated into theory, research, and interventions on Latinos. Likewise, the class nature of U.S. society must be considered, including the relative powerlessness experienced by members of underserved and disenfranchised populations, including many Latinos (1,2). Finally, gender issues in health settings and in the family must be understood in depth in order to develop sound policy and positive social change strategies.

Below we will review key issues of theory that must be addressed in conducting Latino research. These issues include the following: 1) the conscious use of extant theories about the Latino population (as opposed to atheoretical work), 2) the inclusion of essential culture-related constructs and concepts (e.g., acculturation), and 3) the development of a new theory that includes levels of analysis from the micro (personal and individual) to the macro (group, organization, or society).

## Lack of Theory in Latino Health Research

A major limitation of current community intervention studies, including cancer control studies, is that they lack a concep-

tual/theoretical framework that provides a scientific rationale for the proposed intervention and for the mediating variables that would operate to induce changes in cancer risk outcome variables (3). Moreover, research that lacks a theoretical or conceptual framework typically yields findings that stand in isolation from the findings from other studies within a field. These new findings are often difficult to interpret and to integrate within the tapestry of existing knowledge. Research that lacks a theoretical rationale may yield concrete results, although these results may have limited generalizability and applicability to other populations and settings. As noted, much social science research, including health promotion research, lacks a theoretical underpinning, and this problem is particularly pronounced for research on Latinos/Hispanics (4). Such nontheoretical research, when designed to study Hispanic populations, often reflects the researcher's limited appreciation for the importance of theory in research, although it may also reflect the dearth of available theories that are relevant to and that aptly address the sociocultural issues that are of concern to Latinos and their health.<sup>2</sup>

At their worst, nontheoretical studies simply operate as exercises in data collection, where such studies can be described as "having no clear direction" or as "lacking a research thrust."<sup>3</sup> Nontheoretical research often lacks clarity and detail in conceptualization, methods, data analysis plans, and potential conclusions. Such research is inconsistent with more powerful, scientifically grounded approaches.

A literature search of Latino/Hispanic cancer prevention research published in the last 5 years revealed that, of the 31 articles identified, most studies failed to articulate a theoretical model or to clearly operationalize measured constructs. Few of these articles explicitly presented a theory or a model, though a global theoretical framework could be inferred in several of them. To conduct scientifically grounded cancer prevention research with Latinos, a relevant theoretical framework is an in-

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See "Notes" section following "References."



dispensable component, since an appropriate theory provides the following: 1) an informed or correct understanding and application of key concepts, 2) critical and relevant cultural concepts as they influence health outcomes, 3) a framework that suggests how cultural factors may influence participation in cancer prevention, and 4) a context from which to interpret data and results in an integrated fashion such that the whole becomes more than the sum of its parts.

## Clear Definitions

A consequence of omitting theory in Latino health research is the subsequent lack of specificity in the definition of constructs and variables. For example, many studies on cancer-screening knowledge do not specify the conditions under which a factor affects behavior, directly or indirectly, although in some studies the data analyses implicitly assume that knowledge increases in the population induce changes in health behavior (8). By contrast, various studies have noted that information or knowledge about screening is not necessarily related to the actual occurrence of screening behavior (9).

In addition, inferring that certain psychosocial constructs predict or influence health outcomes among Latinos requires an understanding of these constructs within Latino social and cultural contexts. Far too often researchers lack an understanding of a concept's historical trajectory, evolution, and Latino cultural relevance. For example, studying the influence of social networks on cancer-screening participation in Latinos requires knowledge of a network's size, density, composition, and functions, while clearly specifying how these properties affect the health behavior of Latinos (10). Likewise, given the importance of "la familia" (the family and family relations) to Latinos, a detailed understanding of the characteristics of family systems is vital to theory development and program design (11-13). Thus, without clearly defined and well-articulated concepts, a health researcher cannot offer explanations of why Latinos may respond favorably to cancer-screening strategies that incorporate the direct or indirect influence of family or significant others.<sup>4</sup>

## Theory-Based Research

Theory-based research is also important for a practical reason. Interventions developed to reduce risk behaviors are often designed on the basis of what appears to work clinically. Using that which "works" is a good start, but this alone yields a poor conceptual understanding of how the intervention worked. Several well-known theoretical models have filled the gap in conceptual clarity present in many health intervention campaigns. The Health Belief Model (14), the Theory of Reasoned Action (15), the Theory of Planned Behavior (16), and the Social Learning Theory (17) are among the most frequently used models or theoretical frameworks. Indeed, they have been used with some success to design, predict, and understand health behavior in many areas and with different populations, including Latinos.

Nonetheless, it is important to caution against the improper application of such theories when applied to Latinos. While we have strongly encouraged the adoption of theoretical models, we also point out that they must be carefully evaluated for "model

fit" in terms of the Latino cultural experience. To appreciate theoretical and model fit, researchers must be acquainted more than just casually with the culture and dynamics of the Latino population under study, for a failure to understand an ethnic/racial group's culture, language, and traditions may lead to insensitive research designs, research that generates outcomes that are misinterpreted, or research that misses important outcomes (18). At best, this kind of research is unproductive. At worst, it yields conclusions that may damage the population.

Accordingly, principal investigators of any background who work with Latino communities should be required to go periodically into those communities and meet person to person with representatives of the population whom they are studying. Far too often, principal investigators are not fully informed about community history, conflicts, politics, and nuances, yet they draw conclusions from project data about the Latino community, conclusions that are often inappropriate or out of sync with the social, political, and ecological reality of the local Latino community. Having a limited interpretive context for project data not only yields interpretations of marginal validity, but also constitutes poor science, since the conclusions may fail to generate a true picture of the phenomenon under study (18).

We recognize that the health promotion researcher often faces temporal, budgetary, and resource constraints that limit engagement in extensive and in-depth research on the factors that influence cancer-screening behavior. Nonetheless, greater depth of understanding regarding the process of healthy behavior change in Latino populations may yield stronger results on how best to promote cancer-screening behaviors and other types of cancer avoidance.

If Latino cancer research cannot be crafted in accord with a larger and culturally relevant framework, then current one-shot approaches are likely to be repeated, with results that benefit neither the community nor the field of cancer research. In sum, research lacking a historical context and a sound theoretical base in the field of cancer prevention does not yield sound data and conclusions, and it does not advance an understanding of Latina women's participation in cancer prevention activities. In the case of Latino cancer prevention and control, such superficial research may yield poor explanatory power regarding the cancer-screening behaviors of Latinos. Two research efforts reported in this monograph (*see* Ramirez et al. and Flores and Mata) attempt to go beyond such limited approaches.

## Social Action Research and Health Promotion

Social action research (SAR) is an important type of research in the history of Latino groups in the United States, especially with the largest of these groups—the Mexican origin population. The character of this struggle emerged in the 1960s and 1970s with the "Chicano movement," which was guided by strategies aimed at overcoming the relative powerlessness of Chicanos (19,20).<sup>5</sup>

Chicanos conceived, developed, and implemented political strategies, organizations, activities, and tactics throughout the U.S. Southwest and Midwest.<sup>6</sup> Some organizations, such as "La Raza Unida," focused on political alternatives through a third party (22); others focused on "opening up" the universities (23),



while yet others focused on providing access to quality medical care to Latinos (24).

The idea that theory and research could inform social change strategies through social action research is not new, yet for Chicanos in higher education, this notion gained professional legitimacy when the National Association for Chicano Studies (NACS) in 1973 endorsed in its organizational preamble the adherence to an SAR agenda for its members. As a body of professional academics, NACS sought to improve the quality of life for the Mexican origin community via SAR. To do this, Chicano academics forged and reinforced links between the academy and the Chicano community (25).

SAR is defined as theoretically guided and driven research that aims to effectuate a specific positive change or outcome in the targeted community. Economist Ernesto Galarza epitomized this stance through his research, which sought to improve the lives of farmworkers in California (26,27). As a strategy for social change, SAR emphasizes data gathering in conjunction with targeted and specific "macro"-level changes in laws or public policies; likewise, access to health services might need to be increased or delivered, or unjust educational practices halted.

In contrast to basic research that stands aloof from social action, SAR involves a broader agenda that departs from a conscious decision not only to conduct social scientific research, but also to challenge legal statutes and administrative practices, or to attack injustice (28). Given an ambitious agenda, SAR is, in many ways, more difficult to conduct than conventional research. Such policy-relevant research is not unscientific, and variants of this approach that influence social policy are practiced regularly in the fields of economics, social policy, and political science and are found in such prestigious organizations as the Brookings Institution and the Urban Institute.<sup>7</sup>

Social action researchers leave the ivory tower and forge links with community-based organizations that have direct links and ties to the local community. In addition, social action researchers often initiate conversations, dialogue, and even debate with policy makers and gatekeepers on what might be better policies, administrative practices, or laws for the targeted population.<sup>8</sup> For this reason also, sound theory and well-developed theoretical models will aid decision makers in understanding the important individual, group, and community factors that influence health outcomes.

Health promotion, defined as "prevention plus" (30), refers to the dual health promotion goals of preventing disease and enhancing the level of fitness in people who are currently free of disease. Today "community health promotion" studies apply cognitive, behavioral, and social influence methods to behavior change in families, churches, and entire communities (31,32). These health promotion or intervention studies fall in line with the SAR orientation described above.

Moreover, effective and theory-driven health promotion research for Latinos can contribute a deeper understanding of a given health problem, while also aiding in the development of well-designed health promotion intervention that is culturally relevant for Latinos. Health promotion research is typically proactive, as it prompts healthy behavior change in a targeted population. As suggested, not only should sound health promotion research be theory driven, but it also should incorporate a

proactive "social action" approach. Among indigent, culturally different, and/or disenfranchised populations, such as among lower income Latinos, healthy behavior change is attained and maintained only with a comprehensive multilevel intervention that addresses individual, interpersonal, and environmental factors.

Among members of underserved populations, such as Latinos and other people of color, it is becoming apparent that healthy behavior change occurs when members of the targeted population communities are empowered to participate actively as partners in a culturally relevant plan for behavioral and environmental change (33). Thus, from a systems perspective, the process of empowerment involves a multilevel effort, where change efforts concurrently address issues of personal change, change in social supports, and change in environments both proximal and distal (34). For example, a Latina is not fully empowered to participate actively and completely in enhancing her own health if her husband or members of her family are resistant to such efforts (*see* Flores and Mata, this monograph). Barriers may also include a lack of health insurance coverage or a lack of transportation. Thus, health promotion research for Latinos, particularly for those who live in impoverished, unstable environments, must take an SAR approach if it is to effect meaningful health changes. The aforementioned issues underscore the role of gender, race, and class as factors relevant to Latino cancer prevention research.

Accordingly, effective health promotion research with Latino populations should involve the following: 1) *person-level interventions*, such as increasing a woman's preparedness for behavior change by offering educational information on what behaviors enhance health and by developing skills and practices that promote health; 2) *family-level interventions*, such as eliciting social support for healthy behavior change from spouse and family; and 3) *environmental interventions* that eliminate environmental barriers to health care access and that introduce culturally meaningful prompts and reinforcers for initiating and maintaining healthy behavior change. Additionally, as guided by a theoretical framework, a systematic study of the factors and processes involved in promoting health-enhancing behavior change would be conducted using a model that guides the specification, measurement, monitoring, and testing of model-driven hypotheses regarding the antecedents, mediators, and correlated factors that influence targeted health behaviors (35).

The clear specification of a testable measurement model that is based on a culturally relevant theory is the first step toward scientific hypothesis testing and the refinement of extant theory.<sup>9</sup> This process of model definition is well described in the two-step process involved in developing structural equation models: 1) a *measurement model* is developed that serves to identify important theoretical constructs (factors or extent variables) using measured variables as identifiers, and 2) a *structural model* is then identified that serves to test the influences that may exist between the identified factors (36,37).

A well-specified structural model then serves as a "template" or guide for research activity (4). Such a model is useful for identifying relevant variables and the hypothesized relations that may exist between them, as well as for clarifying the characteristics of a proposed intervention that is most likely to be effective for members of a given population.



## Models in SAR

Model building and model testing, as discussed, can be applied to SAR. SAR emphasizes empirical data collection to test the efficacy of an intervention that aims to address an urgent social problem, especially a problem whose solution has public policy implications. The collections of empirical data in a longitudinal design using survey or self-report methods can provide data that measure and test the effects of a prevention intervention as these effects occur across time (*see* Ramirez et al., this monograph).

A promising complement to these quantitative data procedures is the use of unstructured (open-ended) data that can be examined via content analysis (38).<sup>10</sup> The development of robust new methods used to integrate reliably the contents of *quantitative* and *qualitative* data is an important area for new research methodologies that can be applied to cross-cultural and health promotion research (4).

## Problems With Current Approaches

One problem with existing health promotion research approaches in relation to social policy issues is that the time frame generally required to conduct and report on the results of a typical health intervention study is measured in years (e.g., 3-5 years). This lengthy time frame for obtaining results cannot meet the needs of an urgent community social policy issue. By comparison, quick turnaround survey research (e.g., opinion polls) may rapidly “bench mark” a given community social or health policy problem. However, survey research typically lacks a theoretical base. Thus, one gains concrete and timely information, although these data may yield only limited interpretations or understandings within a broader social context. More importantly, survey data that are typically obtained using a cross-sectional design are generally not usable for model testing that shows the effects of an intervention across time.

A practical limitation of current health promotion research, even research that is theory driven, is that such studies often incorporate models that are not well specified for use with a targeted Latino population. In other words, the models used, as applied to Latino populations, omit or exclude one or more variables that are critically important for understanding the sociocultural context that influences the health behavior of various Latinos. This issue is particularly relevant in cross-cultural research, where certain variables can have “culturally specific” properties. That is, these variables have entirely or somewhat different meanings in culture A as compared with culture B. Examples of such variables include the Latino concepts of “*respeto*” (respect and dignity), “*machismo*” (male responsibility), “*salud*” (health), and perhaps even “acculturation.”

Thus, research on the Latino population or Latino subpopulations may be improved by adopting an SAR approach that is designed in accord with a well-articulated model of health behavior among Latinos. Such a model must include the influences of culturally relevant variables and new or emerging cultural constructs that are being measured and studied for the first time. The model must also address design limitations observed in

many current studies regarding the application of current research to social action/social policy concerns (i.e., the need to develop links to community-based groups and policy makers).

Regarding culturally relevant variables, acculturation is an important variable that is related to health outcomes in various Latino populations (40). Researchers view acculturation as a measure of a person's level of cultural involvement and psychological orientation to the Anglo-American and Latino core cultures, as measured by proficiency in English, Spanish, or both languages; by parental heritage; by life experiences in one culture or another; by cultural identification; and even by cultural pride—depending on the scale used to measure acculturation (41).

Given the importance of acculturation issues for most Latinos, a health promotion investigation, theory, and/or model that omits acculturation as a construct and as a measurement variable that examines Latino or Latina health behaviors is likely to be woefully incomplete. Researchers who study Latino populations *must* include acculturation and other culture-related constructs in their models to derive meaningful, useful, and valid studies of Latino health behavior. Here, instead of level of acculturation, many informed researchers use a categorical ethnicity variable, e.g., Hispanic/Latino versus Anglo, which provides a coarse and purely global measure of the rich cultural experiences of Latinos. Such a global measure typically is insufficient, leading to coarse results and ambiguous outcome data. By contrast, the use of culturally relevant variables can yield more valid models for testing not only the influence of the relevant variables (cultural and noncultural), but also the effects of a given health promotion program on various Latino subpopulations as stratified by level of acculturation. Here, the acculturation variable may be modeled as a trait, thus operating as an antecedent variable or, alternatively, as a mediator of program effects. How acculturation is modeled is less critical than the fact that it should be included in a model of Latino or Latina health behavior.

Moreover, the use of acculturation as a variable in theory and model testing in the study of Latino health behavior may also contribute to a further articulation and understanding of the influence of various aspects of acculturation. The various components of acculturation may be observed to exert differential influence on the health-related behaviors of various Latinos. For example, English-language proficiency (speaking and reading) might be related to problems in access to health services (42), whereas affiliation solely with Latino peers may *not* be related to service access but might be strongly related to 1) a Latino's health-related beliefs and 2) a preparedness for changing certain health-related behaviors. Clearly, more research is needed on the components of acculturation (43).

## Emergence of Critical Cultural Concepts

When research is based on the use of the same instruments over time, a gradual accumulation of findings occurs that leads to established generalizations about the population under study. Such repeated findings may then assume a scientific legitimacy. Unfortunately, the mere accumulation of research results across studies and over time may create the illusion of a true under-



standing of a phenomenon. Nonetheless, if such results are based on faulty assumptions, they may lead to established but erroneous conclusions and to a poor ability to predict or to explain the behavior of the targeted population. Only when discontinuities in results begin to surface can a prevailing conceptual "grip" be broken and new concepts or new views begin to emerge. Acculturation research, an area of central importance for the understanding of Latinos, provides some lessons.

To understand the U.S. Latino experience, one must examine the process of cultural change, better known as "acculturation," in the overall research plan. Most studies in cancer prevention fail to take into account differences in cultural background. Some research conducted with Latinas/Hispanics does show an attempt to further differentiate subgroups in this population in order to investigate the differences in health-related characteristics that exist for a variety of reasons [(44,45); Ramirez et al., this monograph]. The most often used measures of cultural change include language of interview or reported language preference, place of origin, ethnic self-identification, and length of residence in the United States. Each of these indicators has been found to reliably distinguish among Latino subgroups, although these variables serve only as "proxy" measures of the true dynamics that drive cultural change among Latinos. In other words, culture and its change are more complex than indicated by these global indices.

Acculturation is often conceptualized as a process of linear change that immigrants to the United States ostensibly undergo throughout their lifetime. This change or "movement" is assumed to occur between a static point A—the culture of origin—and an equally static point B—the adopted culture. In other words, the culture of the country of origin is assumed to consist of relatively stable traditions, norms, and behaviors, while the culture of the host country is also assumed to be uniform and standard. However, consider the example of a poor, young woman who emigrates to the United States from a remote rural area of El Salvador compared with an equally poor, young man who emigrates to the United States from highly urban Mexico City. These two immigrants are highly unlikely to have the same acculturative experiences.

These two non-natives would experience different levels of stress associated with the immigration experience. In addition, they would adopt different cultural traits, depending on whether they settled in a middle-class Euroamerican community, a mostly African-American ghetto, or a Chicano barrio. These different immigration pathways would yield a parallel set of different acculturation "trajectories" (46). Yet, the participation of these and other culturally diverse immigrants in health protective activities is typically encoded by the use of such global cultural indices as mentioned above, without regard for the unique aspects of their differing patterns of cultural change experiences (acculturation). Few researchers have explored the variation in dimensions of acculturation (47). However, with Latino populations, a new generation of acculturation research that is model driven and that expands and deepens the concept of "acculturation" could lead to new and more accurate predictions about the health behavior of various Latinos and Latinas.

In this regard, there exist fallacies in the assumption of a linear, unidirectional process of cultural change (48). Cultural

change typically affects every aspect of a person's life, although the rate of change is not equally distributed across all spheres of a person's life experience (47), and the factors that influence change also vary according to many different factors, such as age, age at immigration, type of reception at point of settlement (hostile and negative versus receptive and supportive), or monetary resources available.

Language use is typically the first behavior that undergoes change, given the need to meet essential needs in the host society, although this need may vary by age: Older immigrants may not be able to learn English as fast as their younger relatives. Specific health beliefs seem to change as a function of language use and education (49). However, we do not know the extent to which more global beliefs about health and illness such as "fatalismo" (fatalism), the perceived role of "nerves" as a cause of disease, or mind/body dualism remain in the Latino culture over several generations, despite other overt changes. Thus, not all processes of change can be captured with a linear model, and not all relevant domains of the Latino cultural experience have been mapped.

The measurement of acculturation is bound not only by the specific aspects of the cultural experience that are measured but also by the actual choice and application of those measures. Researchers often design interventions for different groups of Latinos on the basis of pragmatic considerations. Many find it easier to divide Latinos according to "high" and "low" acculturation levels. But Latinos who fall in the middle of a continuous range that is later dichotomized may not be properly served. This bicultural and bilingual group may be difficult to understand analytically and in terms of prescribed interventions. They may have the language fluency of highly acculturated subjects and a similar level of education and income, but they may also share traditional values and attitudes of the less acculturated subjects. Therefore, predicting the behavior of this group may be difficult. When the Latino community is profiled dichotomously, interventions for this middle-range group may be omitted and appropriate health-related services may not be offered.

Rather than a linear model, a typology that provides guidelines for health education and behavior change based on meaningful subgroup characteristics may be more appropriate. One aspect of "cultural competence" in works with ethnic/racial populations involves the recognition that, even within an ethnic/racial group, there exists "within-group" variability in relation to a few important group characteristics (50). For Latinos/Hispanics, two important health promotion factors or characteristics are *level of acculturation* and *level of literacy* (40). Here, literacy level is measured indirectly within a group or population by level of education, while taking into account differences in the distribution of years of educational access and attainment among persons educated in Latin America, as compared with the educational attainment among persons who have access to education in the United States.

For intervention program planning, the number of different subcultural groups of the targeted population should be minimized, while still capturing fundamental subgroupings that occur within a group that relate to differing health education needs (51). This approach stands in contrast to a "one-size-fits-



all" approach that is often proposed by researchers who are unfamiliar with real variations in the health education needs that exist within an ethnic/racial group.

For Latinos/Hispanics, this strategy yields a two-factor model (acculturation and education) or a 2 by 2 schema that examines the Latino population in terms of *at least* four subgroups: 1) low acculturation-low education, 2) low acculturation-higher education, 3) high acculturation-low education, and 4) high acculturation-higher education. Empirical data from a cancer control study with Latinas by Balcazar et al. (40) offer validation for this schema. Significant differences are observable between these four Latino acculturation-education subgroups as related to socioeconomic indicators (income, employment, and health insurance), to psychological factors (e.g., self-ratings of health and perceptions of satisfaction), to attitudes toward cancer and toward healthy eating, to cancer-related health behavior, and even to cancer screening.

The use of the 2 by 2 schema demonstrates that, for research with Latinos, alternate and empirically valid schemas need to be developed that go beyond the original unilinear acculturation approach.<sup>11</sup> Most certainly, this point is applicable to health promotion and cancer control research with Latino populations.

Perhaps if we study the acculturative experience as the *process* of cultural change within specific domains (health beliefs as a specific cultural domain), we may be able to generate new, more specific predictions about participation in health activities such as cancer screening. Not only do we need integrated models of prevention that are properly evolved from health behavior theories and culturally relevant concepts, but we also need to develop *new* health behavior theories that are derived directly from the Latino experience.

## Ingredients for a Latino-Specific Theory of Health Promotion

Based on the aforementioned issues, the need exists for new approaches toward generating a theory of health promotion and other health-relevant theories that capture the health experiences of Latinos living in the United States. It is not assumed that this uniqueness cannot be shared, but it is assumed that it is the product of the conditions of an ethnic community with a specific historical, political, social, and economic status vis-à-vis a majority population. This approach constitutes an attempt to produce a specific type of social theory regarding a particular group of people of color: Latinos. In this sense, it is a midlevel range theory (52). It is at once an ethnic theory of health that expresses the point of view of an ethnic community regarding its own health behavior, given the ethnic/racial, class, and gender contexts of U.S. society.

Herein we would outline elements for a Latino theory. Those contextual and domain issues previously discussed provide a rudimentary schema. This integrated theory of health promotion begins with a multilevel approach. One must begin with the micro-level or individual and move to the family as possible units of analysis in the given geographical area (dwelling units, neighborhoods, or cities) being studied. In this schema, there are three distinct dimensions for analysis: sociocultural, environmental, and psychological.

At the macro-level, the critical groupings would include the communities, specific nationality groups, and ethnic group patterns. Issues of law, public or health policy, and politics of the community would also be included. In addition, migration history would be considered as well as the sociocultural, environmental, and psychological impacts of migration.<sup>12</sup> Researchers would also consider sociocultural and socioeconomic factors (income, education, occupation, age, and gender) for all Latinos. A less obvious but perhaps equally important factor would be the ethnic/racial background of immigrants. Is this person (a) mestizo (European and Native American background), (b) an American native, or (c) a "Eurolatino"? etc. We propose to use an ethnic/racial category not because we ascribe to it any specific biological significance but because of the importance that ethnic/racial phenotypes have for relations between groups. Thus, racial meanings may be attached in a process of racialization (53), whereby these racial/ethnic characteristics engender biased responses from the health care system such as unfriendly environments or exclusionary practices.

## Conclusion

Our review and critiques of health intervention research among Latinos call for and promote social action or health intervention research that addresses the issues reviewed. New approaches to Latino health promotion that are also applicable to cancer prevention research would benefit from the adoption of the SAR model. That is, we need research models that are sensitive to the conditions (social, political, cultural, and economic) of the population being studied.

It is possible to create health interventions that are contextually based *and* scientifically appropriate. For researchers, this means a greater sensitivity to processes of cultural change and to contexts of cultural norms, values, beliefs, gender differences, etc. More than 20 years of acculturation research indicates that it is not possible to study Latinos as a monolithic group. There are significant variations in health behaviors that correspond to levels of acculturation. Furthermore, it is also necessary to go beyond the global measures of cultural change and study the process within specific health domains. Moreover, we urge researchers who wish to study the health conditions of Latino populations to become much more proactive, not only in examining these conditions but also in ameliorating the poor health conditions that affect Latino populations.

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## Notes

<sup>1</sup>The literature on Latino health has no consensus regarding the preferred terms to use when referring to persons of Latin American heritage who live in the United States. Nationally, the terms "Hispanic" and "Latino" are both used extensively. Given this mixed usage, also found in the current literature, we use the terms "Latino" and "Hispanic" interchangeably.

<sup>2</sup>Recent valuable work is found in (5-7).

<sup>3</sup>Nontheoretical studies are often of poor quality. Governmental review committees such as "Initial Review Groups" (IRGs) often regard nontheoretical social science research as unlikely to make a significant contribution to science.

<sup>4</sup>Examples like this indicate how studies conducted without an understanding of the evolution and current definition of a concept like social network are likely 1) to utilize improper or inaccurate measurements, 2) to draw wrong conclusions, and 3) to generate the misapplication of results and point toward improper cancer-screening approaches. Much time, energy, and money may be wasted.

<sup>5</sup>Chicanos have struggled over quality-of-life issues, especially in the areas of employment (e.g., farmworker unions), education (21), and health.

<sup>6</sup>These struggles occurred in many terrains, including the late Cesar Chavez' United Farmworker's Union in California, Antonio Orendain's Texas Farmworker's Union, and Baldemar Valasquez' work in Ohio with the Farm Labor Organizing Committee.

<sup>7</sup>The decision to conduct SAR usually entails the use of a collaborative research model. This approach is consistent with the multidisciplinary team approach used in biomedical research. For example, in the case involving Texas' denial of public education to undocumented children, researchers collaborated with legal teams from La Raza Legal Alliance, the Center for Human Rights and Constitutional Law (Los Angeles), and MALDEF (the Mexican American Legal

Defense and Education Fund). Similarly, cooperation was sought from the Texas Chicano Education Association and various other local community groups (29).

<sup>8</sup>Seen this way, the task of social action researchers is much more ambitious than simply to survey a population or to understand human dynamics. The challenge is not only to understand and explain human behavior, but also to intervene decisively, based on information gained from scientifically gathered data.

<sup>9</sup>Thus, a model serves as a testable version of the theory from which it is derived. While theory specifies key variables (constructs) and their relationships (linkages) at a conceptual level, a model typically serves as a more concrete specification of the theory at the level of measurement. Thus, a typical model consists of a set of variables and the linkages or effects that exist between these variables.

<sup>10</sup>Likewise, the induction methods of "grounded theory" analysis (39) can generate supplementary data that offer contextual information that may help interpret the quantitative results obtained from testing a proposed structural model.

<sup>11</sup>While the linear approach was fruitful during the 1980s, advances in theory and practice with Latino populations will require new variations in the conceptualization, measurement, and application of acculturation.

<sup>12</sup>Some key migration questions would be asked: (a) Did the person migrate alone or with a family? (b) Was migration voluntary (search for job) or involuntary (victim of political persecution)? (c) Is the Latino group easily granted legal immigration status or not?



# From Ethnography to Intervention: Developing a Breast Cancer Control Program for Latinas

*F. Allan Hubbell, Leo R. Chavez, Shiraz I. Mishra, J. Raul Magana, R. Burciaga Valdez\**

Latinas are less likely than Anglo women to have appropriate breast cancer screening for reasons that may include culturally based beliefs as well as socioeconomic factors. This study employed ethnographic methods to explore breast cancer-related knowledge, attitudes, and behaviors among Latinas, Anglo women, and physicians, tested the generalizability of the findings in a telephone survey of randomly selected women, and used the results to design a culturally sensitive breast cancer control intervention in Orange County, Calif. Respondents for the ethnographic interviews included 28 Salvadoran immigrants, 39 Mexican immigrants, 27 Chicanas (U.S.-born Latinas of Mexican heritage), 27 Anglo women, and 30 physicians selected through organization-based network sampling. Latinas had very different beliefs about risk factors for breast cancer and held more fatalistic attitudes about the disease. For example, they believed that trauma to the breast was among the most important risk factors. Results of a telephone survey of 1225 randomly selected women (269 U.S.-born Latinas, 425 Mexican immigrants, 109 other Latina immigrants, and 422 Anglo women) generally confirmed the dissimilar beliefs among Latinas and Anglo women. The findings influenced our decision to design and pilot-test a breast cancer control intervention based on Bandura's self-efficacy theory and Freire's empowerment pedagogy. The methodology and findings of this study have important implications for future cancer control research and interventions. [Monogr Natl Cancer Inst 18:109-115, 1995]

Recent national surveys have consistently found that Latinas (Hispanic women) are less likely than Anglo (non-Hispanic white) women to have appropriate breast cancer screening (1-3). There are many reasons for these findings. Latinas frequently are poor, lack health insurance, and have inadequate finances to pay for medical care out-of-pocket (4,5). They may also have limited knowledge about cancer-related risk factors and cancer-screening procedures (6-11) and often delay seeking care for cancer-related symptoms (12-14). Moreover, Latinas may have culturally based beliefs about illness and disease that could affect cancer control efforts. For instance, a study (15) found that Latino (Hispanic) and Anglo members of a health maintenance organization, populations that should have similar access to medical care, differed greatly in their beliefs about the causes and symptoms of cancer. In particular, Latinos were more likely

to have fatalistic beliefs about cancer, beliefs that could affect utilization of cancer prevention services. Thus, it is important not only to remove the economic barriers but also to understand the culturally based knowledge, attitudes, and behaviors that may influence the impact of cancer intervention strategies.

When designing this study, we wished to avoid some of the limitations of previous research in this area. Most studies have employed a "deficit knowledge" approach (8), in which investigators have compared respondents' knowledge with existing biomedical information. This method has been successful in measuring knowledge deficits compared with the benchmark data; however, it may not have led to a clear understanding of the respondents' beliefs about the topics. Moreover, the research on Latinos has tended to aggregate recent immigrants and long-term residents, ignoring the potentially important differences in knowledge and attitudes between these groups. These differences could require varying approaches to cancer control intervention strategies.

With these issues in mind, we designed a study that included ethnographic interviews as well as a telephone survey. Ethnography is a research method that explores cultural beliefs and behaviors, usually through qualitative analysis of in-depth interviews. Ethnography focuses on shared cultural knowledge and does not assume that researchers are aware of all relevant questions and issues. Thus, this approach is useful for exploratory studies that are designed to better understand culturally based beliefs and to generate hypotheses for future research. On the other hand, quantitative researchers criticize the ethnographic approach because of the small sample sizes that are often used and because of the qualitative nature of the analysis. To address these concerns, we also conducted a telephone survey of randomly selected respondents to test the generalizability of the ethnographic findings. This article describes the methodology and results of the ethnographic interviews and the telephone survey and summarizes how these findings influenced the choice

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See "Note" section following "References."



and design of a breast cancer control intervention for Latinas in southern California.

## Methods and Results

The Human Subjects Review Committee of the University of California, Irvine, approved the research protocols for the surveys. The investigators obtained oral informed consent from all participants.

### Research Setting

The setting was Orange County, Calif. This county is the third most populous in the state, with the 1990 population estimated at 2 410 556 (16). It covers an area of 786 square miles, is largely urban, and contains 26 cities and numerous unincorporated communities. Approximately 23% of Orange County's population is Latino. Most Latinos are of Mexican heritage; however, an estimated 25 000 immigrants from Central America, particularly from El Salvador, also live in the county.

### Ethnographic Methods

For the ethnographic survey, we designed a semistructured questionnaire that contained more than 300 closed-ended and open-ended inquiries regarding cancer in general, breast cancer, cervical cancer, general access to medical care, access to cancer-screening and treatment services, and demographic characteristics. The closed-ended questions came from the Cancer Control Supplement of the 1987 National Health Interview Survey (NHIS) (17). The open-ended questions came from the NHIS, from focus group encounters, and from advice from the study's Advisory Committee on Cancer Among Latinas, which included professional and lay Latino community members. We pilot-tested the questionnaire by using Latinas who did not participate in the study. A group of health services researchers not involved with the project and the study's advisory committee reviewed the questionnaire for content validity. Bilingual investigators translated the final questionnaire from English to Spanish and back-translated it using well-established methods (18). Interviewers trained in ethnographic methods conducted the survey between August 1991 and August 1992.

Organization-based network sampling (18) served as the method to select the women respondents. Using this approach, one of the investigators made presentations to social, educational, and religious organizations and asked for volunteers. He randomly selected subjects from each study site, with the goal of obtaining a sufficient number of Mexican immigrants, Salvadoran immigrants, Chicanas (U.S.-born Latinas of Mexican heritage), and Anglo women for both qualitative and quantitative ethnographic analyses (19). He determined ethnicity by self-report. Similarly, he selected physician respondents from a sample of primary-care practitioners from the community and from the University of California, Irvine. The interviewers conducted and audiotaped the interviews in either Spanish or English, depending on the respondents' preferences. The interviews lasted between 2 and 4 hours with the women and approximately 1 hour with the physicians.

This article summarizes findings from the questionnaire's sections on knowledge about risk factors, knowledge about

symptoms, and attitudes about prevention and treatment of breast cancer. After obtaining demographic information, the interviewers began the survey with a series of open-ended questions. For the knowledge-related questions, they employed a technique called "free listing" (19), during which they asked respondents to list everything that, for example, could increase the risk of breast cancer and to discuss the reasons for the listings. To ascertain the relative importance of the risk factors, they printed each of them on index cards and asked the respondents to rank order them.

We used qualitative content analysis to analyze the data. Trained research assistants transcribed verbatim the open-ended responses. Using a text-organizing program called AskSam (20), three investigators examined the frequency of citation. They independently evaluated the free listings, the rankings, and the open-ended responses and developed themes from them. Later, they met as a group and discussed the themes until they reached agreement about them. They tested the trustworthiness (validity) of the findings by presenting them to Latinas and Anglo women not involved with the study and asking them to judge the soundness of the results.

### Ethnographic Results

**Respondents.** We interviewed 28 Salvadoran immigrants, 39 Mexican immigrants, 27 Chicanas, 27 Anglo women, and 30 physicians. The women respondents were similar in age. The mean age of the Anglo women, Chicanas, Mexican immigrants, and Salvadoran immigrants was 38, 39, 40, and 35 years, respectively. The Anglo women had the most education, with a mean of 14 years, followed by the Chicanas with 12 years, the Salvadoran immigrants with 8 years, and the Mexican immigrants with 6 years. All of the Anglo women and Chicanas were born in the United States. The Salvadoran immigrants had lived here for an average of 4.5 years, and the Mexican immigrants had lived here for an average of 10.5 years. Fourteen of the 30 physician respondents worked for the University of California, Irvine; the other 16 had community-based practices. The physicians practiced internal medicine, family medicine, or obstetrics and gynecology. Twelve physicians were women, and 18 were men.

**Knowledge and attitudes.** The common breast cancer-related risk factors, symptoms, and attitudes that surfaced during the ethnographic interviews are shown in Table 1. Review of the narrative transcripts revealed that the different groups of respondents expressed dissimilar beliefs about the risk factors and distinctive attitudes about prevention and treatment. The three reviewers reached consensus that there were two cultural models regarding beliefs about breast cancer, a biomedical model shared by physicians and the Anglo women and a Latina model shared by the Chicanas, Mexican immigrants, and Salvadoran immigrants. They confirmed the existence of these models by using a quantitative method called "cultural consensus analysis" (21). The biomedical model emphasized risk factors that have been documented by epidemiologic studies and attitudes generally shared by the biomedical community. The Latina model stressed physical trauma and "bad" behaviors as risk factors and more fatalistic attitudes about prevention and



**Table 1.** Ethnographic findings regarding knowledge and attitudes about breast cancer

Knowledge and attitudes	Groups*
Knowledge about risk factors	
Family history of breast cancer	P, A, C
Age	P
First child after age 30	P
No children	P
Obesity	P
Hormone supplements	P, A
Radiation	P, A, C, M
Early menses	P
High-fat diet	P, A
Smoking	P, A, M, C, S
Lack of medical care	C, M, S
Birth control pills	A, C, M, S
Chemicals in food	A, C, M, S
Breast implants	A, C, M, S
Polluted environment	A, C
Stressful life	A
Illegal drug use	M, S
Blows to the breast	C, M, S
Lack of hygiene	S
Wild lifestyle	S
Excessive breast fondling	M, S
Knowledge about symptoms	
Breast lump	P, A, C, M, S
Bloody discharge from breast	P, A
Painful breast	M, S
Attitudes about prevention and treatment	
If breast cancer is found early, it can be cured.	P, A, C, M, S
I think I would rather not know if I had breast cancer.	M, S
I would undergo breast cancer treatment that is unpleasant or painful if it would improve my chances of living longer.	A, C, M, S
I would be afraid to tell my husband or partner if I had breast cancer because it would affect our relationship.	M, S
I need a mammogram only when I have a breast lump.	C, M, S
There is not much that I can do to prevent breast cancer.	A, C, M, S
I am very likely to get breast cancer in my lifetime.	C, M, S
God gives people breast cancer because they have lived a bad life.	M, S

\*The groups of respondents that commonly cited the risk factors, symptoms, or attitudes listed in the table (P = physicians, A = Anglo women, C = Chicanas, M = Mexican immigrants, and S = Salvadoran immigrants).

treatment. A brief summary of the findings appears below; more detailed accounts of the results appear elsewhere (21,22).

The physicians believed that biomedically recognized risk factors, such as family history of breast cancer, age at menarche, and nulliparity, increased the risk of breast cancer, and they cited breast masses (lumps) as the most common symptom. Their attitudes also reflected their biomedical training. For example, they unanimously agreed that breast cancer could be cured if detected early and disagreed that mammography should be performed only when a breast lump is present. Anglo women were closest to the physicians in their beliefs; however, they did not replicate them. They believed that biomedically recognized risk factors as well as pollution of food and the environment, highly stressful lives, and breast implants were all important risk factors. However, their beliefs about symptoms of breast cancer and their attitudes about the disease generally reflected those of the physicians.

Mexican and Salvadoran immigrants held views very different from those of the physicians and Anglo women. They believed that physical trauma to the breast, incurred through acts

of violence, breast feeding, or even excessive breast fondling, was the most important risk factor for breast cancer. Other factors included behavioral and lifestyle choices (such as taking illegal drugs); lack of medical care and breast implants also were important risk factors. Mexican and Salvadoran immigrants were also more likely to believe that God gives people cancer because they live bad lives and that they needed a mammogram only when they had a breast lump. Chicanas' beliefs and attitudes were similar in some respects to those of the Anglo women and were similar in other respects to those submitted by immigrants. Chicanas thought that biomedically recognized risk factors, lack of medical care, physical trauma, breast implants, and radiation all increased the risk of breast cancer. They were less likely than the immigrants to believe that God gives people cancer, but they were equally likely to think that they did not need a mammogram unless they had a breast lump. Thus, the Chicanas were bicultural in their perceptions of breast cancer.

### Telephone Survey Methods

The ethnographic interviews suggested that Anglo women, Chicanas, Mexican immigrants, and Salvadoran immigrants had different levels of knowledge and varying attitudes about breast cancer. This knowledge allowed us to develop questions that included these disparate beliefs for the telephone survey. For example, we asked the women if breast trauma and excessive breast fondling increased the risk of breast cancer, questions not generally asked on prior surveys. In addition, we included previously used questions from the NHIS and its Cancer Control Supplement (17) and the California Behavioral Risk Factor Surveillance Survey (23). Similar to the ethnographic study, we pilot-tested the questionnaire, tested its content validity, and translated it from English to Spanish to English. The final questionnaire included a previously validated acculturation scale (23) and inquiries about demographic characteristics as well as breast cancer-related knowledge, attitudes, and practices. Trained, bilingual woman interviewers from the Field Research Corporation in San Francisco, Calif., conducted the survey from September 1992 to March 1993.

Eligible participants were English- or Spanish-speaking women 18 years of age or older who were not institutionalized and who identified themselves as Anglo (i.e., Caucasian, white, non-Hispanic white) or Latino (Hispanic or more specific ethnic identifiers such as Mexican or Mexican-American). We did not include physicians in the telephone survey; however, a randomly selected group of physicians later completed a similar survey by mail. We are currently analyzing those data. The telephone survey used a cross-sectional sample of random-digit telephone listings to identify eligible subjects. Both listed and unlisted numbers appeared in the listings, avoiding potential bias due to exclusion of households with unlisted numbers (24). The survey randomly selected both households and respondents within households—the woman 18 years or older who had the most recent birthday. Latina respondents could choose to answer the questions in Spanish or English.

We used the two-tailed chi-square test to analyze the categorical data and logistic regression analysis to evaluate the relative contribution of ethnicity in predicting knowledge and attitudes about cervical cancer. The predictor variables included



age, marital status, household income, insurance status, education, and employment status. For the Latina sample only, we added acculturation and country of birth to the analysis. The results appear as adjusted odds ratios (ORs) with 95% confidence intervals (CIs).

## Telephone Survey Results

**Respondents.** Interviewers made 21 171 calls, of which 1561 (7.4%) were to eligible women. They completed interviews with 1225 of the 1561 eligible women, for a cooperation rate of 78.5% [defined as the number of completed interviews divided by the sum of the completed interviews and refusals by eligible women, i.e., 1225/(1225 + 336)]. Of the remaining calls, 9850 (46.5%) were to business or disconnected numbers, 8002 (37.8%) were to ineligible households, 1315 (6.2%) were to women who refused to participate before eligibility screening, and 443 (2.1%) were to households that did not answer.

Of the 1225 women interviewed, 803 were Latinas (269 U.S.-born Latinas, 425 Mexican immigrants, and 109 immigrants from other Latin American countries) and 422 were Anglo women. Their demographic characteristics appear in Table 2. When compared with the Anglo women, the Latinas were younger (mean age = 43.8 years for Anglo women versus 33.9

years for Latinas), had less education (mean = 14.5 years versus 10.9 years), had lower household income levels (median yearly income = \$48 000 versus \$22 000), and were less likely to have health insurance (92% versus 67%). Among the Latinas, the mean age of the Mexican immigrants (31.2 years) was lower than that of the U.S.-born Latinas (36.5 years) and the other immigrants (38.4 years). The Mexican immigrants also had the least education (9.3 years for Mexican immigrants versus 13.3 years for U.S.-born Latinas and 10.9 years for other immigrants) and had the lowest median yearly family income (\$16 800 for Mexican immigrants versus \$36 000 for U.S.-born Latinas and \$21 600 for other immigrants). The majority of Latinas were born in Mexico (53%) and had low acculturation levels (62%).

**Knowledge and attitudes.** Table 3 displays bivariate analysis of knowledge and attitudes about breast cancer among the Anglo women and Latinas as a group as well as by country of birth. Latinas were less likely than Anglo women to embrace medically accepted risk factors, such as family history of breast cancer, and more likely to believe that other factors, such as breast trauma, increased the risk of contracting breast cancer. A smaller proportion of Latinas than Anglo women believed that a breast lump, bloody discharge from the breast, and puckering of the skin over the breast were symptoms of breast cancer. Moreover, more Latinas believed that women needed a mammogram only when they had a breast lump, would fear telling their husbands if they had breast cancer, and would rather not know if they had the disease. When analyzed by country of birth, the U.S.-born Latinas' knowledge about risk factors, knowledge about symptoms, and attitudes about prevention and treatment often differed significantly from those of immigrants from Mexico and other Central American countries. Indeed, the U.S.-born Latinas' answers usually corresponded more closely with those of the Anglo women than with those of the immigrants.

Findings from the multivariate analysis generally supported those from the bivariate analysis (Table 4). After we controlled for age, marital status, household income, insurance status, education, and employment status, the Latinas were still less likely than the Anglo women to believe that family history of breast cancer and age were risk factors for breast cancer and were more likely to think that breast implants, breast trauma, multiple sexual partners, use of antibiotics, and excessive breast fondling increased breast cancer risk. They were also less likely to know that breast lumps, bloody discharge from the breast, and puckering of the breast skin can be symptoms of breast cancer. Moreover, the Latinas more often preferred not to know if they had breast cancer, would be afraid to tell their husbands, and believed that they were very likely to get breast cancer. Perhaps most alarmingly, they were nearly three times as likely to believe that they needed a mammogram only when they had a breast lump.

To determine ethnic-specific predictors of knowledge and attitudes, we added acculturation and country of birth as predictor variables for the Latina sample. Less acculturated Latinas were less likely to believe that family history of breast cancer and age increased risk but were more likely to believe that breast trauma, excessive breast fondling, fear, lack of medical care, taking antibiotics, multiple sexual partners, and worrying about breast

Table 2. Demographic characteristics of telephone survey respondents\*

Characteristic	Anglos (n = 422), %	Latinas (n = 803), %
Age, y		
<40	47	74
40-49	23	15
>49	31	11
Education, y		
0-6	<1	22
7-12	25	43
>12	75	35
Annual household income, \$		
<10 000	7	18
10 000-29 999	23	44
>29 999	70	39
Health insurance		
Insured	92	67
Not insured	8	33
Employment status		
Employed full-time	50	43
Employed part-time	12	12
Not employed	38	45
Country of birth		
United States	100	34
Mexico	0	53
Other	0	13
Acculturation		
More	NA	38
Less	NA	62
Years in the United States		
<5	0	18
≥5	100	82
Language of interview		
English	100	44
Spanish	0	56

\*NA = not applicable. The total proportions may not equal 100% because of rounding error.



Table 3. Telephone survey findings regarding knowledge and attitudes about breast cancer

			Latinas by country of birth		
	Anglos (n = 422), % agree	All Latinas (n = 803), % agree	United States (n = 269), % agree	Mexico (n = 425), % agree	Other (n = 109), % agree
Knowledge about risk factors					
Family history of breast cancer	98*	86	97†	78	89
Age	74*	60	71†	54	57
Chemicals in food	71	69	66	69	74
Breast implants	70*	89	78†	94	94
Birth control pills	69	71	68	71	77
Radiation	60	58	56	57	61
Breast trauma	41*	74	55†	85	77
First child after age 30	30	34	21†	42	33
Worrying about breast cancer	28*	39	23†	46	50
Fate	23*	37	25†	43	39
Early menses	18	14	13	14	13
Multiple sexual partners	9*	40	12†	59	41
Antibiotics	8*	30	11†	44	21
Excessive breast fondling	6*	30	11†	42	29
Knowledge about symptoms					
Breast lump	98*	89	97†	84	84
Bloody discharge from breast	93*	77	89†	70	71
Puckering of breast skin	74*	58	68†	51	56
Painful breast	72	74	74	74	69
Differing breast size	51	56	54	57	58
Scaly breast skin	44	44	46	43	46
Attitudes about prevention and treatment					
If breast cancer is found early, it can be cured.	98	98	97	98	99
I would undergo breast cancer treatment that is unpleasant or painful if it would improve my chances of living longer.	93	94	94	94	96
I am very likely to get breast cancer in my lifetime.	32*	57	43†	66	61
There is not much I can do to prevent breast cancer.	22	30	25	35	25
I need a mammogram only when I have a breast lump.	11*	35	19†	47	31
I would be afraid to tell my husband or partner if I had breast cancer because it would affect our relationship.	3*	15	7†	22	12
I think I would rather not know if I had breast cancer.	3*	17	6†	24	12

\* $P < .001$  between Anglo women and all Latinas.† $P < .001$  between U.S.-born Latinas, Mexicans, and other immigrants.

cancer were risk factors. This group also was more likely to express the attitudes that they would rather not know if they had breast cancer, that they were very likely to get this cancer, and that they would be afraid to tell their spouse if they had breast cancer. Latinas born outside the United States were less likely to believe that symptoms included breast lumps, bloody discharge from the breast, and puckering of the breast skin. They were also more likely to believe that they needed a mammogram only when they had a breast lump.

## Discussion

Findings from ethnographic interviews suggested that Latinas had very different levels of knowledge and dissimilar attitudes about breast cancer than Anglo women and physicians. For example, the Latinas believed that physical trauma to the breast and "bad" behaviors, such as illegal drug use, were the most important risk factors for breast cancer. They also expressed more fatalistic attitudes about the disease, such as the belief that God gave women breast cancer to punish them for living bad lives. In addition, the Latinas were much more likely to believe that they needed a mammogram only if they had a breast lump, a belief with important implications for breast cancer control ef-

forts. Results of a large telephone survey of randomly selected women generally supported the ethnographic findings and revealed that less acculturated Latinas were more likely to have misconceptions about risk factors and to express fatalistic attitudes.

The study has two principal limitations. The generalizability of the ethnographic findings may be questioned because the number of subjects was small and the sample was not random. We addressed this issue by conducting the large telephone survey of randomly selected households. In addition, the telephone survey findings may not be generalizable to families without telephones. While Latino households in Orange County have relatively high telephone subscription rates (approximately 94%), Latino families without telephones have lower incomes than those with telephones (25,26). Nationwide, families without telephones have less access to medical care (27) and, therefore, may have less access to cancer-related information and less knowledge about breast cancer.

Our findings provided the necessary foundation to design a culturally sensitive breast cancer control intervention aimed at improving Latinas' knowledge and attitudes about breast cancer and increasing their use of breast self-examination and mammography. Because the beliefs of the Latinas, particularly those

**Table 4.** Adjusted ORs of Latino ethnicity as a predictor of knowledge and attitudes about breast cancer\*

	OR	95% CI	P
<b>Knowledge about risk factors</b>			
Family history of breast cancer	0.2	0.1-0.4	.000
Age	0.6	0.4-0.8	.000
Chemicals in food	0.9	0.7-1.3	ns
Breast implants	2.3	1.7-3.2	.000
Birth control pills	1.0	0.7-1.3	ns
Radiation	0.9	0.7-1.2	ns
First child after age 30	1.0	0.8-1.4	ns
Worrying about breast cancer	1.3	1.0-1.8	ns
Fate	1.2	0.9-1.7	ns
Early menses	0.7	0.5-1.2	ns
Breast trauma	3.6	2.7-4.8	.000
Multiple sexual partners	4.6	3.1-6.9	.000
Antibiotics	3.0	1.9-4.6	.000
Excessive breast fondling	4.6	2.9-7.2	.000
<b>Knowledge about symptoms</b>			
Breast lump	0.3	0.1-0.5	.000
Bloody discharge from breast	0.4	0.3-0.6	.000
Puckering of breast skin	0.6	0.4-0.7	.000
Painful breast	1.0	0.8-1.4	ns
Differing breast size	1.3	1.0-1.7	ns
Scaly breast skin	1.0	0.8-1.4	ns
<b>Attitudes</b>			
I can be cured.	2.0	0.8-5.0	ns
I would rather not know.	4.9	2.5-9.5	.000
I would undergo treatment.	1.3	0.7-2.2	ns
I'm afraid to tell my husband.	5.0	2.5-9.9	.000
I need a mammogram only when I have a breast lump.	2.9	2.0-4.2	.000
I can't prevent it.	1.4	1.0-1.9	.048
I am very likely to get it.	2.1	1.6-2.7	.000

\*Predictor variables included age (<40 = 0; ≥40 = 1), marital status (married = 0; not married = 1), household income (<\$30 000 = 0; ≥\$30 000 = 1), insurance status (insured = 0; not insured = 1), education (<high school = 0; ≥high school = 1), and employment status (employed = 0; not employed and not in the work force = 1). ns = not significant.

with low acculturation levels, diverged so greatly from those of the biomedical community, we believed that it was important to develop an intervention specifically for them. Thus, the intervention took into account the relatively low levels of formal education, the low income of the population, and the preference for the Spanish language. Moreover, we believed that it was imperative to incorporate the Latinas' beliefs into the intervention rather than dismissing them as silly or folkloric. Decontextualization of the health problem from the belief systems and daily routines of the target population may have diminished the effectiveness of many previous health education efforts (28). Finally, we wished to design an intervention that would have the best chance to change not only knowledge and attitudes but also behavior among Latinas.

With these considerations in mind, we modeled the intervention on Bandura's theory of behavioral change (28,29) and on Freire's empowerment pedagogy (30,31). In brief, Bandura's theory predicts that individuals will change their beliefs about their own self-efficacy once they have experienced mastery of a task from effective performance of it. An increased sense of self-efficacy then leads to changes in behavior, which may then lead to improved outcomes. For example, a woman will be more likely to perform breast self-examination if she feels competent

to do it, and if she detects breast cancer early, she improves her chances for a good outcome. The intervention also employs lessons learned by Freire (30,31) during his literacy campaigns in developing countries that were based on Bandura's theoretical perspective. Latinas in our study share many cultural and socioeconomic attributes, such as low levels of formal education, with groups that have already been helped by his empowering pedagogy. Freire found that individuals with low educational attainment absorb new information best when it is presented in a way that relates to their current environment and life circumstances. Thus, the educational process should allow students to introduce circumstances that affect their beliefs about the health problem, in this case breast cancer, into the educational setting. The educator then empowers the students to make breast cancer control their own problem instead of the educator's problem.

Currently, we are testing an empowerment model intervention in a university-affiliated community clinic in Orange County. Latinas older than 40 years who have not received a mammogram for at least 2 years participate in four biweekly educational sessions based on Freire's methodology (Table 5). During each session, a health educator poses questions to the participants that are designed to encourage thought and discussion about the potential impact of breast cancer on their lives, about risk factors and symptoms of breast cancer, and about prevention and treatment of the disease. The educator then guides the group to come up with solutions to the problem of breast cancer control. We obtain measures of breast cancer-related knowledge, attitudes, and practices prior to, immediately following, and 6 weeks after the intervention in the experimental group and in a control group who did not receive the intervention. Results of this pilot test will allow us to determine the effectiveness of

**Table 5.** Empowerment model intervention: educational content\*

**Module 1: Breast Cancer: Myths and Facts.** This module focuses on procedural rules of the sessions, reasons for staying healthy, what each member already knows about breast cancer, and myths and facts regarding the disease. The establishment of procedural rules by the group is a major means for instituting empowerment early in the process. This module also initiates entry into the "problem-posing" pedagogy. By discussing knowledge and by learning myths and facts, the women begin to assess how much they know. This stage of the intervention assists each woman in establishing a base-line level of efficacy against which she can assess the extent to which she "owns" the problem of breast cancer control.

**Module 2: Breast Cancer Risk Factors and Symptoms.** This module focuses on ways in which the women are in control of their own health, on learning about risk factors and symptoms of breast cancer, and on discussing three types of early breast cancer detection (i.e., clinical breast examinations, breast self-examination, and mammography). The women also set goals in relation to the information presented—another step designed to elevate their own expectations of themselves.

**Module 3: Breast Self-examinations.** This module addresses the reasons why clinical breast examinations and breast self-examinations may not be performed, how to perform self-examination correctly, goals related to breast self-examination, and a plan of action for breast cancer detection. The women also practice breast self-examinations with models.

**Module 4: Mammograms and Follow-up.** This module focuses on what a mammogram is and how it is carried out, obtaining access to mammography in the community through lists of doctors and clinics providing mammograms, role playing for requesting mammograms, and the importance of following up on abnormal findings.

\*The intervention consists of four educational sessions lasting approximately 2 hours each and occurring twice weekly.



the empowerment methodology in improving breast cancer control among Latinas.

The methodology and findings of this study have important implications for future cancer control research and interventions. First of all, by allowing respondents to express their own beliefs in an open-ended way, ethnographic interviews can lead to a better understanding of cancer-related knowledge, attitudes, and behaviors. Through a large telephone survey, we found the ethnographic results to be widely generalizable. Investigators should consider the use of ethnography in future investigations of inadequately studied populations. Second, the findings suggest that cancer control educational materials could be improved by addressing culturally based beliefs that conflict with those of the Anglo population. An empowerment intervention that, like the ethnographic interviews, allows interaction between Latinas and the educator and incorporates culturally based beliefs into the educational process may improve knowledge and attitudes about breast cancer and increase the use of cancer control procedures. Results from our ongoing pilot study will test this hypothesis.

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# Community Level Cancer Control in a Texas Barrio: Part I—Theoretical Basis, Implementation, and Process Evaluation

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A theory-based program that used peer modeling and a network of peer communicators to promote breast and cervical cancer screening was designed and implemented in a barrio of San Antonio with a population of approximately 25 000 adult women. The implementation process was evaluated and documented through field notes, archival documents, content analyses, interviews, surveys, etc. Over a 21-month period, a total of 156 news stories and a network for distribution of more than 80 000 print pieces carried messages about positive role models who were receiving Pap smears and mammograms. A group of 85 volunteers were recruited to promote screening; these volunteers reached 2000-3000 women each month with personal contacts in which cancer screening was encouraged. A small group of volunteers offered particularly intensive assistance to their peers, e.g., helping them to make and keep appointments for screening examinations. The theoretical communication model for the program, which maximizes audience and community participation as sources and channels for messages, was well suited for the cross-cultural application presented here. [Monogr Natl Cancer Inst 18:117-122, 1995]

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Hispanic women tend to lack sufficient cancer screening (1-4). For example, Harlan et al. (5) found that Hispanic women were more likely to say that Pap smears were necessary but were the least likely to receive them; those who spoke only Spanish or mostly Spanish were the least likely to have had a Pap smear within the last 3 years. Hispanics are more inclined to have misconceptions about cancer and are less aware of the warning signs of cancer than the general population (6-8). The lowest level of use of only medical care in this country is by Hispanics (1), mostly because of conditions of poverty and employment in lower-skilled jobs that do not provide health insurance. Complicated registration procedures and difficult-to-understand educational materials are additional barriers when accessing an unfamiliar medical system (8,9). Low-income Mexican-Americans in Texas have a particular pattern of cancer risk. Rates of most cancers are lower than those among Anglo-Americans in Texas, at least partly because of low rates of tobacco and alcohol use, especially among women. However, even with lower rates of cervical cancer than their Anglo

counterparts, Mexican-American women in Texas do have higher mortality, apparently because female reproductive cancers are frequently detected too late (10). Dietary behaviors also are problematic, with inadequate vitamin intake and lower levels of fat avoidance by Mexican-Americans than those found among Anglo counterparts or high-income counterparts (11).

According to Ramirez et al. (12), one effective way of reaching Mexican-Americans is through media-based public health campaigns. However, such programs are effective only when designed and implemented in a culturally meaningful and sensitive manner, based on the heterogeneity in levels of acculturation within the Mexican-American community. One theory-based approach to behavior change has been demonstrated to be effective in other cross-cultural applications. This diffusion acceleration approach (13) combines two communication techniques: 1) the use of early adopters of the desired behaviors as mass media role models in documentary and journalistic formats, and 2) organization and mobilization of natural social networks to prompt and reinforce imitation of the role models. The best-known example of the effectiveness of these techniques is provided by the North Karelia Project in Finland (14-17). Based on the North Karelia Project, the *Programa A Su Salud* was developed (1985-1990) to encourage smoking prevention and cessation among Hispanic-Americans (18,19). In a quasiexperimental study that evaluated the campaign, rates of smoking cessation were significantly higher in Eagle Pass, Tex., the treatment city, than in a matched comparison city (20).

There are other ongoing projects seeking to reduce health risk behaviors, such as *Companeros en la Salud* and *Por La Vida*, cancer prevention programs directed to Hispanic-Latino and Latino women, respectively (21). Other such programs are described in articles in this monograph. This article presents program methods and implementation evaluation results from a study demonstrating such a program for breast and cervical can-

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cer screening and nutrition education in an urban, Mexican-American barrio of San Antonio, Tex. Preliminary results from the summative evaluation of effects on screening rates are presented in the following article (22). The main objectives of the program are to 1) increase screening and compliance with Pap smear recommendations among Mexican-American women 18 years and older, and 2) increase screening and compliance with mammography recommendations among Mexican-American women 40 years and older. During the course of the study, controversy developed that led to new age guidelines recommending regular mammography for all women over the age of 50. Younger women were encouraged to receive mammograms if they had a family history of breast cancer. The program combined media and community activities within a six-census tract area in San Antonio's predominantly Mexican-American Westside. The following sections detail the program design, implementation process evaluation, and results from the first 3 years of activity.

## Methods

The demonstration activities were conducted by The University of Texas Health Science Centers at San Antonio and Houston, with cosponsorship from the San Antonio Metropolitan Health District and the Texas Department of Health. Six census tracts on the west side of San Antonio were selected for evaluative research. The program activities were concentrated in, but not limited to, that area, which contained approximately 25 000 women, of whom approximately one third were older than 40 years of age. This is a barrio community with copious unmet needs, including unpaved streets and unremoved garbage. While there has been increasing attention to the provision of health care services, it is commonly agreed that too many women, especially if they speak only Spanish, have not learned why or how to take advantage of the services that are offered.

## Media Campaign

*Programa A Su Salud* used several forms of mass media, including print, radio, and television in both English and Spanish language formats, to present role models. These individuals were recruited from the community and each reflected the same socioeconomic, ethnic, and cultural characteristics as the targeted audience. The only difference was their newly adopted behavior. Through social modeling, the program promoted healthier behaviors and created motivation for action. This combined strategy (media and community activities) sought to modify the target population's preferences and perception of risk, barriers, benefits, social pressure, self-efficacy, and outcome expectations.

Data on community information-seeking habits and other media preferences were obtained from libraries, marketing departments, and focus groups with community members. Then local mass media channels (i.e., television, radio, and newspapers) were prioritized and solicited to establish partnerships. These led to formalized agreements stipulating the interests and responsibilities of each party. Each media channel agreed to provide regular (usually weekly) airtime or column space and to provide reporters, cameras, and other needed media personnel. Program staff from the Health Science Centers pledged to provide a role model along with interview questions, background material, and expert commentary on the topic. To

facilitate this process, negotiation information covered the project's genesis, examples of role modeling, tentative media schedules, and content outlines. Exclusive association with one of each major media channels per intervention community was preferred (i.e., campaign programming appeared on one television station, one radio station, and one major daily newspaper per intervention community). However, different-language media were not considered competitive within most communities because broadcasters regarded different languages as drawing distinctly different audiences. Therefore, it was acceptable to have programming over one English and one Spanish television station within the same intervention area.

Focus groups were designed to obtain qualitative understanding of a select group's participation and orientation to a given topic of discussion (12). Analysis of the terminology, expressions, and other verbal communication that surface in the group yields useful guidelines for program promotion or program message design (18). For this program, eight focus groups with 56 participants in each were organized to learn more about knowledge and perceptions of breast and cervical cancers, health care services, preventive health practices, nutrition, media habits, and other related topics. Participants were drawn from a cross-section of the target community. Focus group outcomes revealed a sense of helplessness about cancer, with fatalistic attitudes and either ignorance or confusion about the types and frequency of screening procedures. Many of the respondents questioned the effectiveness of the procedures. When asked about barriers to screening, the principal reasons cited were shame and cost. Related to language usage, there was a preference for bilingual material, so Spanish and English were both used in the intervention community. Focus group participants heartily endorsed the idea of using role models from the community who had made behavior changes (i.e., participated in screening or changed diet behavior) as the source for each message. The groups also suggested that a medical expert should be included when clarification of technical data or special emphasis was required. Over the course of the study, the form and content of media products were routinely screened by additional focus groups within the context of social, cultural, and traditional mores and perceived values of the community. This also cultivated a sense of ownership within the community of the themes and imagery used.

Role models were identified through a number of community organizations (churches, social and civic organizations, community health clinics, small businesses, and schools) and through community outreach by the community volunteers and program staff. Low-income, urban Hispanics, 16-65 years of age, were the core criteria used to select role models. Screening required structured interviews and then assignment to medium of presentation, depending on the strength of the models' story and their preference to be on television, on radio, or in print.

The statements in the role model interviews were analyzed and organized by specific cognitive influences on behavior (Table 1). These concepts were drawn from a variety of theories to maximize the effectiveness of education, skills training, and persuasion (23). Based on this analysis and guided by a monthly topic schedule, media messages were produced in the form of news stories, articles, scripts, flyers, etc. This method allowed



**Table 1.** Theoretical sources for message content areas

Cognitive influences on behavior	Theoretical sources
Self-efficacy (skill)	Social cognitive learning theory (Bandura, 1986)
Response efficacy (benefits)	Health belief model (Becker, 1974)
Attitudes (evaluation)	Theory of reasoned action (Fishbein and Ajzen, 1975)
Perceived risk	Health belief model (Becker, 1974)
Perceived barriers	Health belief model (Becker, 1974)
Perceived social norms	Theory of reasoned action (Fishbein and Ajzen, 1975)
Perceived incentives/consequences	Social cognitive learning theory (Bandura, 1986)

simplification of interview analysis, provided clarity of the behavioral message and ease of content classification, and facilitated campaign monitoring (24). The theoretical concepts provided guidance for the interviewer and headline or tag line writing. For example, an interview to probe self-efficacy would ask about how the person came to feel in control of their own screening status. Specific questions for self-efficacy would include the following: "If you want to get a mammogram, how sure are you that you could do it? Why? How has this changed in the past few years?" An interview about response efficacy would focus on perceptions about whether cancer screening can indeed prolong life.

A chief goal of the intervention was to maintain a continuous stream of messages across as many different media channels as possible. Other goals were exclusive programming with specific media, preservation of the role model as the focus of all messages, and rotation of behavioral/cognitive concepts. We planned for regular bilingual programming to appear in television, radio, and print. The media plan included weekly television and newspaper stories and monthly materials distribution. The goal was to present approximately one new message in some form each week.

Actual use of radio in San Antonio averaged 1 hour per month. Talk shows were either taped for later broadcast or offered live, which stimulated immediate audience interaction. A role model and medical expert would accompany a project staff member and the radio personality. Weekly English language columns appeared in *The Sun*, a weekly insert of *The San Antonio Express News*, the major daily newspaper with a circulation of 220 000. A Spanish language column occurred biweekly in *La Prensa*, which had a circulation of 50 000, but largely targeted the Westside's Mexican-American neighborhoods. Regular evening television newscasts featured *Salud* programming over KWEX, the local Spanish language Univision affiliate. In addition, each week from August to December 1993, programming occurred over a local cable access channel that aired programs featuring role model stories and had medical experts with project staff as moderators. All presentations were categorized and tabulated for later analysis and implementation evaluation.

### Narrowcast Media

A number of project materials were developed to promote and reinforce the mass media messages and to present modeling

stories in a small media format. The small media facilitates interpersonal contact by volunteers and the community. Other project-generated materials were specifically designed to aid volunteer network maintenance. At the beginning of each month, community bulletins were distributed throughout the community by volunteers and outreach staff. The bulletin contained a calendar of role model mass media stories listing the channel, time, and program title. It also included role model stories with pictures that focused on the behavioral objectives predetermined for that month. Important information, such as clinical cancer-screening sites, fee schedules, phone numbers, and clinic times, were provided. This bilingual publication strove to meet 6th-grade reading levels or lower, expressed content graphically whenever possible, and added a visual variety of color, shape, and form.

To encourage additional interpersonal contact with the community, a very simple (Xerox-copy quality) bilingual, mid-month recipe flyer was produced. The recipe flyer typically promoted a traditional menu item (featuring foods low in fat and high in vitamins and fiber), accompanied by a picture of its author (either a volunteer or other community member). A brief statement by a role model that conformed to the monthly topic area was included. A bilingual, 180-page cookbook containing original recipes from the kitchens of role models and volunteers was also produced. In addition to 47 recipes, the book contains preparation guidelines, different food groups, daily nutritional requirements, fat and fiber facts, and pictures of the volunteers. Each recipe was tested by nutritionists and dietitians in a Houston test kitchen to confirm quality and taste and to ensure what a "dash of this" or a "handful of that" really meant. Amounts of fiber, fat, and caloric content are provided for each recipe, along with a helpful tip for preparation.

A volunteer newsletter, entitled *Saludos*, was also provided and mailed on a quarterly basis to the networkers or volunteers. The newsletter provided educational information to the volunteers as well as current news about the project and other volunteers. The newsletter was intended to reinforce volunteer participation, to provide internal network communication, and to publicly acknowledge their work. Volunteer activities and special occasions, such as birthdays, graduations, and anniversaries, were announced. As a benefit of volunteerism, each volunteer received a complimentary cookbook.

### Community Organization

According to the communication approach presented here, the most effective teachers are those who teach by example and offer encouragement for the development of new behaviors. The objectives of the community networkers were to identify role models who demonstrate the knowledge, attitudes, and skills needed to prevent cancer and to prompt and reinforce imitation of those models. The project recruited networkers to promote breast and cervical cancer screening and appropriate nutritional behaviors among members of the community and to encourage community members to listen, view, and read project-produced media messages. A full-time community coordinator supervised community outreach activities, networker recruitment, and the efforts of two part-time community outreach workers. The role



of outreach workers was to support the community coordinator by helping to identify, recruit, train, and maintain networkers. This was achieved by making personal contact with their neighbors (through phone calls and home visits), recruiting networkers, distributing small media, and supporting networker maintenance activities (i.e., helping to organize refresher classes). Recruitment of volunteer networkers required networking among opinion leaders, institutions, and community groups. Organizations, agencies, small retailers, and churches within the study area provided names of potential networkers, and appointments were made with interested individuals and organizations.

The main function of the networker was to regularly distribute small media materials while providing positive reinforcement for project activity and personal behavior changes. Training was offered on a monthly basis. It consisted of role-playing community bulletin distribution while paying special attention to sociocultural and interpersonal communication issues. Observance of cultural traditions was emphasized, such as respecting other people's schedules, maintaining confidentiality in their contacts, and never approaching a person of the opposite sex who might be alone in the house. Basic training techniques included the proper use of positive social reinforcement and avoidance of prejudice, criticism, and conflict. Training was bilingual and lay testimonies reinforced project benefits, goals, and personal self-efficacy.

Each refresher session offered new and/or practical information for the networker, reported on the volunteer network, and encouraged networker leadership development. Training sessions were designed to familiarize networkers with health care technologies to alleviate fears and alienation associated with medical care and procedures. Refresher sessions included tours of health care sites and presentations by speakers with a specialty in breast and/or cervical cancer detection, treatment, and research. Networkers were encouraged to suggest topics for future refresher sessions. By seating everyone in a circle and mixing staff and networkers, interaction increased and reticence to express real needs and/or experiences decreased.

All networker maintenance activities sought to be interactive and supportive. The networkers formally enrolled in the project by completing or assisting in the completion of a "networker profile form" (i.e., personal background data, networker's interests, and the number of persons a networker could regularly contact each month). In addition to their formal social reinforcement role, the networkers also were instrumental in identifying role models within the community.

Keeping networkers motivated is as much art as social science. Some incentives developed by the *Salud* program included identification buttons with pictures, completion of a training certificate, a handbag with educational materials, *Salud* pins, and cookbooks for networkers after 6 months of participation. *Salud* networkers were also recognized in the networker quarterly newsletter. Personal events were acknowledged with cards in the mail (i.e., birthday, anniversary, death, etc.). In addition, an annual summer picnic and Christmas party provided group celebrations. After the first year of program activity, beginning in the summer of 1993, a set of organizational sites was recruited to augment distribution of small media. These included small businesses, churches, senior nutrition centers, and

community health centers. Based on the interest of their leadership and on the number of customers, members, etc., each site agreed to distribute an appropriate number of materials.

## Implementation and Process Evaluation

Several forms were designed to facilitate process data collection and monitor the conceptual and applied development of *Programa A Su Salud*. Regular staff meetings were held with the purpose of reviewing community and media target activities and accomplishment and to aid in problem solving. This activity also helped to gather and confirm field data that were not collected by other means or forms. All data were systematized, coded, and entered using a commercial relational database program and then analyzed by the project evaluation staff. The different elements were: 1) an organization contact form to identify type of group contact, contact person, number of potential volunteers, etc.; 2) a volunteer recruitment form to register potential volunteers who desire to enroll in the project; 3) a training evaluation form to evaluate each training session so that adjustments could be made to improve effectiveness; 4) a volunteer profile form, updated weekly, that provides an inventory of the volunteers with the basic data needed for further evaluation; 5) a media production form, completed monthly, to record all mass media activities featured monthly; 6) a small media distribution form, recorded monthly, to record distribution of materials by volunteers and sites; 7) a volunteer survey form, distributed quarterly, to evaluate project activities, volunteer interests, and needs; and 8) a role model inventory form, updated periodically, to provide an inventory of the role models participating in the project.

## Results

### Media Distribution and Content

The distribution of small media material is described in Table 2. A total of approximately 84 000 pieces was recorded over 2 years of activity. Distribution increased in the second half of 1993, when the organizational sites were activated. Since that time, businesses (mostly small shops and grocery stores) have been the major route of distribution. The number of messages carried by the three mass media channels is presented in Table 3. A total of 156 messages were recorded during seven quarters. This amounted to an average of 7.5 stories per month, with the majority appearing in newspapers.

Each small media piece carried one to three separate role modeling messages. The mass media messages usually consisted of a simple story about a role model. In the broadcast media, these ranged from 2 to 10 minutes in length, depending on the format and time of day. The newspaper stories were typically 10 column inches or more, with a photograph or artwork to illustrate the message. To illustrate the actual distribution of message content, we examined field notes, other records, and actual newspaper stories in print for 60 separate stories to categorize information according to the theoretical message content areas used in the campaign. Each story contained more than one content area, and we were able to identify a total of 111 specifically intended messages in the 60 stories. The results



**Table 2.** Small media distribution, October 1992 - December 1994

Sites	1992	1993				1994		Total
	4th quarter	1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	
Volunteers (n = 85)	3939	3233	2485	3085	2055	3650	3575	22 022
Businesses* (n = 74)	0	0	0	8487	6200	9520	8670	32 877
Churches (n = 2)	0	0	0	2099	1244	2045	2106	7494
Nutrition sites (n = 7)	0	0	550	3423	2195	3630	3255	13 053
Health services (n = 7)	0	0	0	1783	1280	2220	3080	8363
Totals	3939	3233	3035	18 877	12 974	21 065	20 686	83 809

\*Includes: restaurants, grocery stores, pharmacies, beauty salons, flower shops. Participation of businesses increased over time.

**Table 3.** Quarterly mass media placement by type

Media type	1992	1993				1994		Total
	4th quarter	1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	
Television	1	0	0	14	4	8	3	30
Radio	6	6	4	0	1	1	1	19
Newspaper	21	18	17	18	16	13	4	107
Totals	28	24	21	32	21	22	8	156

of this analysis are shown in Table 4. Self-efficacy and response efficacy stories were the top categories, followed by evaluative attitudes, risk perceptions, overcoming barriers, and social influences. These reflected both the content of the actual material provided by the role models and our finding, assessed through focus groups, that people need to learn they can control their own risk of death because cancer screening is effective as well as acceptable and low in cost. Examples of the messages are provided in Table 5.

Records of the implementation and process evaluation indicate that 85 volunteers (82 females and three males) were recruited. Demographic data on the volunteer network were collected at the time of their activation into *Programa A Su Salud*. Quarterly surveys sampled a portion of the volunteer network measuring changes in health knowledge, attitudes, and behaviors during the course of their participation in the project. Results showed that 92% were females; the average age was 49 years, with education levels of 7th to 8th grade. The most frequently cited reasons for becoming a volunteer were a desire to help other women, an awareness of the importance of cancer prevention, and the need for better nutrition practices.

**Table 4.** Media content by theoretical concept

Theoretical content	No. of distinct theoretical concepts
Self-efficacy	26
Response efficacy	25
Attitudes	14
Perceived risk	13
Barriers	10
Social support	9
Perceived incentives/consequences	6
Perceived norms	5

To assess their activity, data from the volunteer surveys were tabulated. Sixty volunteers participated in the survey; they reported four to 100 contacts per month in which they encouraged peers to read or view program messages and to learn from and imitate the role models. Examples of specific information that role models reported giving include "low cost examinations, female doctors available, Saturday appointments." All were satisfied with their activity; 11 had found and referred role models to be featured in the media campaign. Twenty-four (40%) reported special activities that went beyond their role as communicators. Each of these women helped an average of 12 of their peers to make screening appointments; an average of six were followed by each volunteer to make sure that the appointment was kept. Examples of these reported activities included the following: "talked to friends and family [to get their help], called [the clinic] together with them, took them to the clinic." Interestingly, we found that networkers who initially committed

**Table 5.** Illustrations of role model stories using different theoretical concepts

Theoretical concepts	Examples provided by role models
Self-efficacy	By asking for a Pap smear, Mrs. A. took control of her own health; it was a good thing because the doctor found cancer; Mrs. A. had an operation
Response efficacy	Mrs. A. was 39 then; today she is 85 and feeling fine
Perceived norms	"More and more of my friends are getting mammograms"
Attitudes	"I would rather spend a little to find disease early enough to do something about it"
Perceived risk	"Everyone can develop cancer"
Perceived barriers	"I used to get embarrassed"
Perceived incentives/consequences	"If I do not go, it could be worse"

to contact many people were often those who contacted the least in practice, while networkers who were most productive were more realistic from the start and often exceeded their expectations. Age was a good predictor of interpersonal contacts. Of the 10 networkers who distributed the most calendars, one half were more than 60 years old. Prior volunteerism and organizational experience were good predictors of activity but only fair predictors of actual clinic referrals.

## Discussion

*Programa A Su Salud* exemplifies culturally sensitive health promotion at the community level. Based on encouraging preliminary findings presented in a companion article, we are expanding application of these techniques to other Hispanic populations and additional areas of cancer control. The theoretical model that was applied in this study combines peer modeling and peer organization for networking. This means that all messages come from the audience in the form of role model stories and that the community itself distributes them through the peer leader network. This removes and overcomes cultural and linguistic barriers to communication to guarantee that nearly everyone can be reached with a relevant message from an appropriate source. Each component of the program (i.e., community networkers, media production, and evaluation [both qualitative and quantitative]) involved individuals from the community and investigators who were bilingual and bicultural. This collaboration at each level led to a more effective communication strategy. In addition, specific aspects of the Mexican-American culture were preserved in the delivery and reinforcement of the health behavior messages. "la familia" (family), "respeto" (respect), "simpatia" (understanding), and "el idioma" (language) were part of all each program element.

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# Community Level Cancer Control in a Texas Barrio: Part II—Base-line and Preliminary Outcome Findings

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**In a quasiexperimental demonstration study, screening rates for breast and cervical cancers were measured among Mexican-American women in selected areas of San Antonio and Houston, Tex. This research was primarily designed to evaluate a cancer-screening promotion program in San Antonio by comparing changes in screening rates in panels from the two barrio communities. In a base-line population survey, we found a small, but significant, proportion of women (10%-15%) lacking Pap smears and a larger proportion (30%-40%) lacking mammography. In a panel study following women who lacked screening at base line, there was a trend toward greater Pap smear use among younger women and a significant increase in mammography for all age groups in San Antonio compared with groups in Houston. Although there was a difference in language use between the communities, rates of newly initiated screening within the communities were similar among monolingual Spanish speakers and among those who used English, supporting the hypothesis that the program increased both groups' participation in breast-cancer screening. [Monogr Natl Cancer Inst 18:123-126, 1995]**

This report presents methods and results from the quasiexperimental panel study that was designed to evaluate the theory-based communication program to promote participation in cancer screening among women in the barrio of San Antonio described in (1). The study was implemented in selected census tracts in two urban communities, one receiving the program (San Antonio) and the other serving as a reference (Houston). Base-line measurements were taken in 1991 and a follow-up panel study was conducted in 1994 with women who reported inadequate cancer screening at base line. The panel design was selected as the best choice for a quasiexperimental study with noncomparable groups (2). Although individual-level random assignment is the preferred method from a statistical point of view, it is not appropriate for evaluation of community-level programs, such as those implemented by Ramirez and McAlister (3). The community-level, quasiexperimental research design has been widely employed in published studies of other areas of disease control, particularly in studies of smoking cessation (4). While results must be interpreted carefully, this research design can

yield useful evidence about the potential effectiveness of community-level, behavior-change campaigns (5-7). The panel design, with repeated measures of individuals, is the most efficient choice for assessing experimental effects in comparisons between whole units not randomly assigned to treatment or control conditions (2). It is influenced by treatment-measurement interaction, but canvassing with brief interviews can be considered as part of the treatment itself. In a study of smoking cessation patterned after the study by Meyer et al. (8), a quasiexperimental panel design yielded evidence of program effects on verified rates of smoking cessation in a Mexican border city in Texas (9). The present research employs that design to evaluate program effects on cancer-screening participation in an urban barrio in Texas.

Although there have been some interesting case studies (10,11), results from a community-level demonstration study employing a community-level, quasiexperimental design have not been reported in the literature on action to promote screening among Mexican-American women. Some promising experimental results have been reported in other populations (12). While a major issue determining screening is its reimbursement (13), it is also necessary to promote the services across cultural barriers. To learn how this can be effectively accomplished, controlled experiments must be carried out in community settings. This report presents the base-line and preliminary outcome findings from a community-level, quasi-experimental, panel study of the effects of screening promotion.

## Methods

The 1980 census found that 44 722 persons lived in the six selected census tracts located on San Antonio's west side. Data from the 1990 census were not

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See "Note" section following "References."



yet available when the study was conducted. According to the 1980 census, 53% were women, 8750 of whom were over the age of 40. The median age of these women was 25.6 years, the median household income was \$8061, and 86% of the residents spoke Spanish. The selected area was composed of 703 residential blocks, of which 336 were selected to participate in the enumeration phase. A total of 1576 residences were subsequently selected from these residential blocks for the personal enumeration interview. In the control site of Houston, 41 562 persons lived in the seven selected census tracts located in the Navigation area. Forty-eight percent of the residents were women, of whom 5686 were estimated to be over the age of 40. According to the 1980 census, the median age was 24.2 years, the median household income was \$12 134, and 80% of the residents spoke Spanish. Of the 703 residential blocks that constituted the defined control site, 430 were chosen in the enumeration phase. A total of 1482 households were selected by a computer program for the personal enumeration interview.

Eligible survey participants were selected with the use of a multistage sampling procedure. First, areas composed of adjacent census tracts in Houston and San Antonio were selected and matched according to the proportion of residents who indicated Hispanic ethnicity in the 1980 census. Second, within each selected census tract area, a computer program selected residential blocks from census records fed to a computer program. Third, the selected residential blocks were visually inspected by the field supervisor, who recorded each address manually onto a preprinted map. Fourth, a computer program systematically selected every third residence, identifying those households eligible for enumeration. Fifth, personal enumeration interviews were conducted to determine whether the residence was in fact inhabited and whether the inhabitants were of Mexican-American origin, establishing their gender and age. Only one Mexican-American woman 18 years or older per household was eligible to participate in the base-line interview. If only one woman was available, she was selected for the interview. If more than one woman was eligible, an algorithm was used that selected the person with a birthday most recent to the date of interview.

The survey was designed to be administered as a personal interview conducted either in English or in Spanish at the residence of the respondent. Twenty bilingual and bicultural interviewers were recruited from the community and attended a 3-day training workshop, after which they went into the field. The workshop included role playing, skills for contacting respondents, the interview protocol, and response-coding practice. In addition, interviewers received a manual of operations and met with the on-site project manager on a regular basis.

Data collection began in October 1991 and ended in May 1992. Data were collected for a total of 1804 Mexican-American women in face-to-face interviews lasting between 40 and 90 minutes, depending on whether the food-frequency module survey was included. Before the interview started, a consent form that stressed confidentiality, voluntary participation, and the significance of the project was read and signed by the participant. Respondents were paid \$10 by mail for completing the interview.

Items included in the Women's Health Survey were pooled from existing questionnaires that had been previously implemented with Hispanic- and/or Spanish-speaking populations. Identical items were being used concurrently in a study in El Paso, and were pretested in San Antonio. The follow-up panel interview administered to women consenting to participate in the panel study consisted of questions addressing perceived health, general health, cervical and breast cancer screening, attitudes and norms associated with both cancer-screening procedures, social support, cancer awareness, media exposure, and tobacco and alcohol use. These questions had been included in the base-line survey and did not undergo any major modifications. The questionnaire took 15-20 minutes to complete over the phone. Respondents were read an informed-consent statement. If they completed the interview, they were paid \$10 by mail.

The panel study was carried out during the spring and summer of 1994. Selection of the panel-study participants was based on self-reports of compliance with the National Cancer Institute's cancer-screening guidelines, provided in the base-line interview survey. Basically, a case was selected according to three criteria: age of the respondent, reported mammogram, and Pap-smear screening. Of the 1804 women who participated in the base-line survey, 683 cases were identified as eligible to participate following these criteria: 1) Women younger than 40 years of age were selected if they had never had a Pap smear or had not completed a Pap smear in the 2 years prior to the interview; 2) women older than 40 years of age were selected if they had never had a Pap smear or had not completed a Pap smear in the 2 years prior to the interview; and 3) women older than 40 years of age were selected if they had never had a mammogram or had not

completed a mammogram in the 2 years prior to the interview. Women older than 40 years of age did not have to meet the two cancer-screening compliance criteria (Pap smear and mammogram screening) to be selected for the panel study. If they did not comply with one of the two cancer-screening procedures, they were selected for the interview. Women younger than 40 years were selected only if they had not complied with Pap-smear screening recommendations, as indicated in number one above. Seventy-six percent of the cases selected with the algorithm ( $n = 612$ ) had a telephone number listed in the database. Of this total, there was a further decrease in the number of potential respondents who could be reached because the phones were disconnected, sometimes with the number assigned to a new person, or the person had moved away without leaving a new phone number. Because the phone was disconnected or the respondent no longer lived at that household, 215 cases were eliminated from the list. Among the 397 potential respondents we identified, a minimum of five interview attempts were made. The total number of interviews completed for this panel study was 309, with a response rate of 78%. In Houston, there were 187 cases available for interviewing, and 150 were completed (80%). In San Antonio, there were 203 cases available for interview, and 159 were completed (78.3%).

## Results and Discussion

Some characteristics of the two base-line study samples are shown in Table 1. The two samples are quite different in several ways. In Houston, there were approximately twice as many participants who were born in Mexico and who identified themselves as Mexican rather than as Mexican-American. Compared with those in Houston, women in San Antonio were twice as likely to use English in the interview. These findings of non-comparability showed a greater difference between the two barrios than was anticipated from the 1980 census data, and they contributed to our decision to use a panel study for program evaluation. The differences probably reflect important aspects of the two communities. San Antonio was founded by Spanish-speaking peoples over 300 years ago and, despite some turmoil in the past century and a half, it now has a well-established Mexican-American population that has gained considerable dominance over the affairs of the city as a whole and is now the electoral majority. Although there are many recent immigrants from Mexico in the barrio, it is primarily a second, third, or much older population with a long history of exposure to the English-language culture. Houston was founded after the period of Spanish dominance of Texas, and its barrio is a modern development populated by many recent immigrants, especially in the past 10-20 years.

The primary variables of interest for this study are rates of participation in screening to detect female reproductive cancer: Pap smear and mammography. We found four main types of participation deficiency, with some overlap between certain categories. Some women had never had one or both examinations, and

Table 1. Cultural characteristics of study samples

	San Antonio	Houston	Chi-square	P
No. of subjects	892	906		
Ethnic self-identification				
Mexican (versus Mexican-American, Hispanic, other)	31.2	58.4	135	<.0001
Fewer than 7 years' education	33.5	49.3	46	<.0001
Born in Mexico	31.0	63.0	186	<.0001
Interviewed in Spanish	39.8	68.5	150	<.0001



others had not been re-examined in more than 2 years. The proportions in these categories are shown in Table 2. Women are grouped by numbers above and below 40 years of age because that was the consensus age for mammography recommendations at the time the study began. The data show that, despite the differences in community characteristics, the two study groups were comparable with regard to the primary-study outcome. These findings mirror results of other surveys of Hispanic women in Texas, showing a significant subgroup that lacks even the basic preventive care provided by a Pap smear. Lack of mammography was much more common, mainly reflecting its cost and newness.

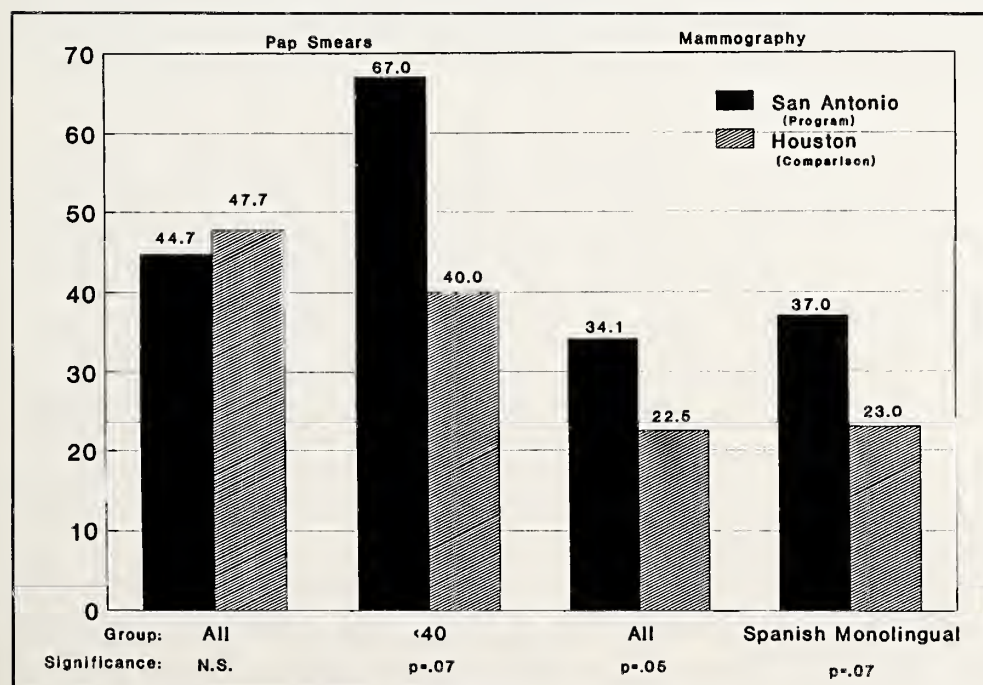
Most of the respondents who participated in the panel-study phone survey were older than 40 years of age (82.4%) and from San Antonio (54.9%). Most respondents were primarily Spanish speakers, as indicated by the language chosen to complete the interview (73.6%). The primary outcome of interest for the panel study was the rate at which women obtained Pap smears and mammograms. These were the same women whose reported lack of screening is presented in Table 2. Rates of Pap smear and mammography are shown in Fig. 1. Over the approximate 2-year interval that the panel was followed, 111 women reported having a Pap smear and 70 women reported having a mammogram. For Pap smears, there was no overall difference in the percentage of women in San Antonio or Houston who obtained the examination (45%-48%). Among women under the age of 40 who had never had a Pap smear or who had not had one in the past 2 years ( $n = 68$ ), more panel respondents reported having a Pap smear in San Antonio (67%) than in Houston (40%). However, because of the small sample size, this difference was only at the borderline of significance ( $\chi^2 = 3.4$ ;  $df = 1$ ;  $P = .065$ ). For women in the panel in San Antonio, the proportion of respondents who reported having a mammogram (34.1%) was significantly greater ( $\chi^2 = 4.0$ ;  $df = 1$ ;  $P = .045$ ) than that in Houston (22.5%). For women over the age of 50, for whom mammography was most consistently recommended

**Table 2.** Proportions of women lacking screening by type, age, and city

	San Antonio*	Houston*
Women aged $\leq 40$ y who had never received a Pap smear or had not received one within 2 years	.15 (405)	.15 (434)
Women aged $\geq 40$ y who had never received a Pap smear	.09 (493)	.10 (474)
Women aged $\leq 40$ y who had never received a mammogram or had not received one within 2 years	.39 (493)	.37 (474)
Women aged $\geq 40$ y who had never received a mammogram	.31 (493)	.30 (474)

\*Values in parentheses = No. of subjects.

during the intervention period, a similar difference was observed that, because of the smaller sample size, was not statistically significant. These results do not support the hypothesis that a program-treatment effect was present with respect to obtaining Pap smears, but they are consistent with the hypothesized program impact on mammography. Although trends were in the hypothesized direction, differences in mammography rates were not significantly different within age subgroups, e.g.,  $\geq 50$  years of age. This is primarily because of small sample sizes for the subgroups. Consensus on recommended ages for mammography screening changed after the first year of the study, and the program recommendations were revised accordingly. However, the sampling design did not anticipate this shift in objectives, and the community itself may have been confused by the revision. Because women under the age of 40 are recommended to obtain mammograms if they have a family history of breast cancer, the program displayed role models promoting the services for younger age groups. This makes the entire panel group a good indicator of the program's overall effect.



**Fig. 1.** Percentage of panel participants receiving examinations by city and type.

Because the Houston sample included more Mexican- and Spanish-speaking women, it is possible that the difference in mammography rates was due to an underlying tendency for these women not to receive the screening examinations. To determine whether the difference in mammography rates might be due to this base-line difference between groups, separate analyses were conducted for the two language groups. For monolingual Spanish speakers, Pap smear rates again showed no significant differences between the program and comparison groups, but there was a nonsignificant trend ( $\chi^2 = 3.2$ ;  $df = 1$ ;  $P < .074$ ) toward higher rates of mammography in the San Antonio (program) panel (37%;  $n = 65$ ) than in the Houston comparison group (23%;  $n = 81$ ). This trend indicates that the overall difference in rates could not be due to the base-line non-comparability of groups with respect to language use.

There are several explanations that might account for the evidence of a treatment effect only for mammograms. In both Houston and San Antonio, new services offered mammograms at lower costs, and there was much national and regional publicity about the examination and its merit. This may have combined with the local program activities to produce the effect on mammography rates. For Pap smears, no new initiatives were offered to lower already low costs or increase already good availability. This may have prevented the program activities from having much effect on Pap smear rates. Another possibility is that the program had more effect on mammography because there were simply more women in need of the examination, which was relatively new to some women in the community. The difference in effects may be understood in terms of the differences between midterm and late adopters of a health innovation (14). The kind of program that was organized in San Antonio might have been appropriate for the early and midterm adopters who were just beginning to use mammography services, but not for the women who still avoided or missed Pap smears. These latter women may be characterized as late adopters and thus may be less amenable to community-level programs. In our subsequent research, we are investigating whether more intensive personal contact will have measurable

effects on Pap-smear rates among women who have never had that examination.

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## Note

M.-E. Fernandez-Esquer and A. L. McAlister shared equally in the writing of this report; A. L. McAlister and A. G. Ramirez were the principal and co-principal investigators; F. Trevino and L. Pulley were responsible for the base-line surveys; M.-E. Fernandez-Esquer conducted the panel study with assistance from I. Torres; and R. Villarreal, S. Hu, and Q. Zhang assisted in the management and analysis of data.



# Mobilizing Churches for Health Promotion in Latino Communities: *Compañeros en la Salud*

Felipe G. Castro, John Elder, Kathryn Coe, Helen M. Tafoya-Barraza, Santiago Moratto, Nadia Campbell, Greg Talavera\*

*Compañeros en la Salud* (Partners in Health) is a 3-year project funded by the National Cancer Institute to conduct a church-based health promotion program whose aim is to reduce the risk of breast, cervical, and diet-related cancers in Latino/Hispanic women by increasing their knowledge of preventive behaviors, motivating healthy behavior change, and increasing their access to and utilization of preventive health services. From a systems perspective, churches serve as miniature, dynamic communities that present an opportunity for developing and implementing a program of health promotion. An analysis of church, *Promotora* (peer health worker), and participant characteristics from the preintervention base-line data revealed a naturally occurring segmentation of churches by congregation size and denomination. The Catholic churches almost exclusively were larger, whereas the Protestant churches almost exclusively were smaller. An analysis of the psychosocial characteristics of the various Latino women, when stratified by church congregation size, revealed that the women from the smaller, Protestant churches were poorer, had a lower level of acculturation, and had lower lifetime rates of clinical breast examinations. These results suggested greater resource deficits and a relatively higher need for *Promotora* outreach services for women from the smaller, Protestant churches. Implications are presented for differential approaches to effective health promotion among various types of churches. [Monogr Natl Cancer Inst 18:127-135, 1995]

Concern over the high levels of cancer mortality experienced by Hispanic/Latino<sup>1</sup> women has resulted in the need to mobilize social networks and social systems, such as churches, in order to deliver health promotion interventions directed toward the prevention and early diagnosis of cancer to large numbers of women. In the past, schools and community health centers have been the focus of most community health promotion programs, while other institutions have on occasion provided a forum for health promotion (1). One such institution is the church, an institution in which the well-being of members is a central concern. For Latinos, the church may be particularly effective as a forum, because the church has traditionally served as an important source of cultural education and fellowship.

## Aims of *Compañeros en la Salud*

*Compañeros en la Salud* (Partners in Health) is a 3-year project conducted in predominantly Hispanic/Latino Protestant

and Catholic churches located in the greater Phoenix, Ariz., area, a large metropolitan area of the southwestern United States. Funded by the National Cancer Institute, the general aim of the project has been to reduce the risk of breast, cervical, and diet-related cancers in Latino women by increasing their knowledge of preventive behaviors, teaching skills in health behavior change, and increasing their access to and utilization of preventive health services. A central factor in this systems mobilization was to promote church-community participation by training and deploying a team of *Promotoras*, or peer health workers, who would serve as health educators and resource persons for health referral.

## Overview of Project Structure and Process

To succinctly illustrate the history and operations of the *Compañeros* project, Fig. 1 presents a schematic analysis of its structure and activities. A grant from the National Cancer Institute was awarded to the Arizona State University in the name of the Principal Investigator, on the basis of a review committee's evaluation of the *Compañeros* proposal's scientific merit and potential contribution to social need (#1; Fig. 1) The Principal Investigator hired a Project Director, and both consolidated a working relationship between the Hispanic Research Center and the School of Nursing (#2). These investigators then hired other research staff (#3) and student assistants (#4) to create the *Compañeros* project staff.

The *Compañeros* staff then identified and visited several local churches that had a high percentage of Hispanic members in order to encourage priests/ministers and other members of the church leadership to participate as *Compañeros* project churches (#5; Fig. 1). A total of 14 churches were ultimately recruited; seven churches were then randomly assigned to the cancer control (intervention) condition, and the other seven churches were randomly assigned to the family mental health (comparison) condition.

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See "Notes" section following "References."

## Compañeros en la Salud: A University-Church-Health Agency Partnership

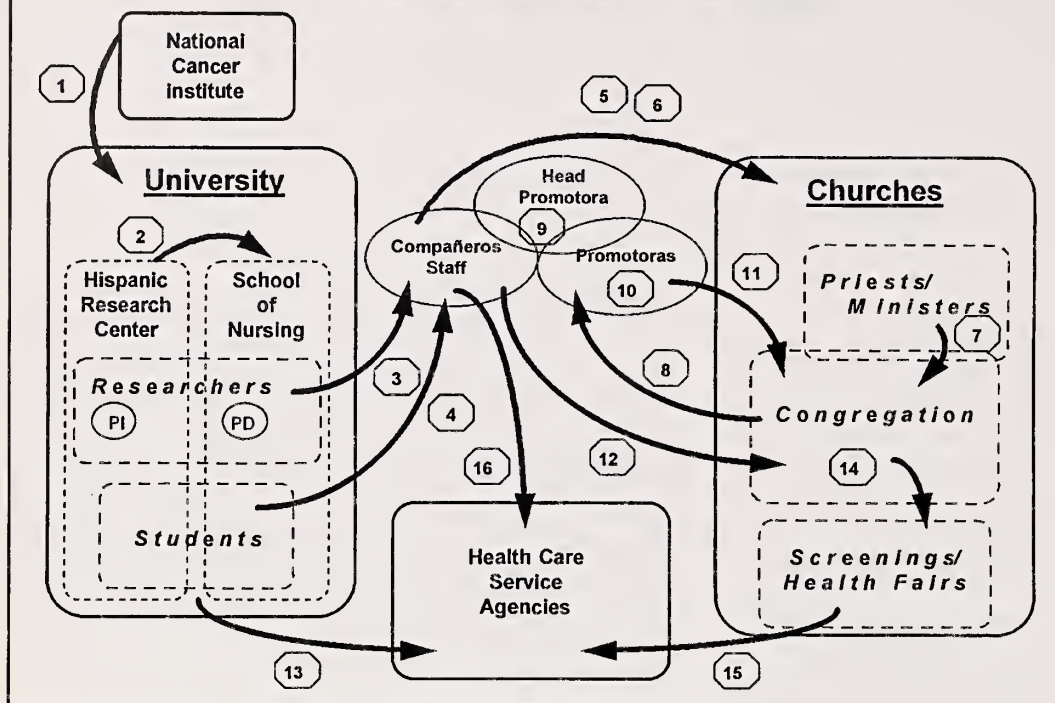


Fig. 1. Schematic analysis of the structure and activities of the *Compañeros* project. PI = Principal Investigator; PD = Project Director.

A base-line telephone survey was then conducted by the data collection and management subgroup of the *Compañeros* staff (#6; Fig. 1). The purpose of this survey was to collect base-line data on 10 areas of health, including breast cancer, cervical cancer, and diet-related behavior. Within each church, group meetings were then held with women who were identified by the priests/ministers as active members of the church (#7). The goal was to recruit those women who would be interested in and capable of serving as church *Promotoras*. For each of the 14 churches, from among the original group of Latino women candidates, one to three women showed a sustained interest in participating (qualified on the basis of basic screening criteria) and ultimately joined the *Compañeros* project as *Promotoras* (#8).

From this group of *Promotoras*, one woman (who years before had successfully battled breast cancer) emerged as the *Head Promotora* (#9; Fig. 1). The *Head Promotora* was delegated leadership responsibilities and rallied other *Promotoras* around *Compañeros* activities. All *Promotoras* received a structured program of health promotion skills training (#10). In addition, the cancer control and family mental health groups of *Promotoras*, respectively, received classes and training specific to their assigned area of intervention.

Once trained, the *Promotoras* in collaboration with the *Compañeros* staff held health education classes and health promotion activities within the participating churches (#11; Fig. 1). Throughout the project, *Compañeros* staff worked with the *Promotoras*, maintained visibility within the church communities, and sustained working relationships with the priests/ministers and with the congregation. *Compañeros* staff occasionally recruited a new *Promotora*, because a *Promotora* stepped down or moved away (#12).

Concurrently, the *Compañeros* staff through the Hispanic Research Center and the School of Nursing also developed a second partnership with local health agencies in order to procure free or low-cost health services from various medical service agencies; these agencies included the county medical center, county and other public clinics, voluntary agencies such as the local chapter of the American Cancer Society Planned Parenthood, local community-based organizations, and private hospitals and clinics (#13; Fig. 1). In addition, as part of this partnership, the head oncologist from the county hospital's cancer center participated regularly as a consultant on a variety of cancer issues and at times facilitated referrals for treatment.

This evolving partnership with churches and with the local health care community set the stage for the continued provision of health promotion activities by *Compañeros* staff (#12; Fig. 1) within the various churches. These health education activities included inviting congregation members to attend health fairs that were conducted periodically on weekends at various project churches on a rotating basis (#14). These health fairs featured cancer prevention activities including mammography screenings, instructions in breast self-examination, cervical cancer screenings, and general well-woman examinations. In addition, Spanish-language literature and on-site health consultations were available at the various "health information stations" that were located throughout the health fair. Participants included *Compañeros* staff, student nurses and faculty from the School of Nursing, the *Promotoras*, student translators, and health providers from one or more health care agencies.

Women who were found to have a health problem at the health fair or on follow-up examinations were referred to the appropriate health care agency (#15; Fig. 1). Many times, the



available services were insufficient to meet the observed health problem, and *Compañeros* staff and the *Promotoras* conducted additional follow-up on a case-by-case basis in order to procure the needed resources to fully address the health problem that had been detected at the health fair (#16).

## Need for *Promotoras* in Indigent Latino Communities

There is a marked underutilization of regular and preventive health care services by Mexican-Americans when compared with Anglo-Americans (non-Hispanic whites) (2). This underutilization is due primarily to limited access to health care services. For many Mexican-Americans, this limited access is a consequence of being "working poor," which means that they work in low-paying jobs that offer few or no insurance benefits (3). For example, data from the 1989 Current Population Survey and from the 1982-1984 Hispanic Health and Nutrition Examination Survey have indicated, respectively, that 36.9% and 36.2% of Mexican-Americans were uninsured, but, by comparison, less than 12% of non-Hispanic whites were uninsured (3). As a result of being uninsured or underinsured, a large percentage of Mexican-Americans do not have a regular source of medical care, often endure pain and illness until symptoms become severe, and thus more often seek medical care from hospital emergency rooms (4,5).

Another health systems barrier facing Latinos involves the health provider's lack of understanding or disregard for many Latino women's view of health and illness and their beliefs about how one should treat illness and on how one seeks health care within the Latino cultures (6). Other barriers to effective access to health services for Latino women can include lack of transportation, lack of support from spouse or family, and lack of understanding of the manner in which to obtain available services in the local community. An interactive barrier also involves the patient-provider relationship. Many Latino women, particularly more *traditional* Latino women, experience shame and embarrassment in discussing sexual matters. This psychological discomfort operates as a barrier in the presence of a culturally uninformed physician, especially if the physician does not speak or understand Spanish.

In the Western biomedical model, medical doctors have relied on nurses and social workers to oversee discharge and follow-up care. Unfortunately, this approach does little to offer preventive services. This underservicing of nonmajority populations prompts the need for a different approach, one that is proactive in offering outreach. Given the background and characteristics of the *Promotora*, she has the ability to encourage and convince women in the community to use the health services that are available to them. With a growing awareness of these issues, several service-oriented agencies in the state of Arizona and elsewhere have begun taking a careful look at the *Promotora* approach.

From a systems perspective, churches are self-contained, community-based social systems. While Latinos trace their roots to many countries, despite differences in nationalities among church members, churches serve as places where various Latinos can share similar beliefs. Accordingly, Hispanic/Latino

churches serve as community sites where low-acculturated, Spanish-speaking, poorly educated women can be reached with health education messages. Consequently, churches serve as a "channel" in which health promotion innovations can be presented and disseminated (7). Given the central role of the church in the Latino community and its culture, we chose churches as the vehicle for cancer risk reduction that would reach even hard-to-reach members of the community.

## Background: The *Promotora* Approach

The *Promotora* approach to health care has grown from naturally occurring adaptive practices that developed in indigenous communities in Mexico, Central America, and South America. Remaining healthy is a survival task worldwide. Thus, historically, medical practitioners have evolved in all cultures in response to the need within the community or village for leadership regarding the health of the tribe or community. Given women's role as caretakers in many cultures, those women who emerged as most knowledgeable about the use of herbs and ways of remedying health problems evolved as local healers. Local residents would then consult those women for their knowledge of ways to cure various ills, thus casting these women (and sometimes men) into the role of prestigious community healers. Some of these healers became known as *Curanderas* or *Curanderos*. Persons who become *Curanderas(as)* have a strong spiritual orientation and assert that they themselves do not provide cures but act instead as a servant of God who promotes God's will.

*Promotoras* should not be confused with *Curanderas*. *Promotoras* do not assert or suggest that they have healing capabilities. However, *Promotoras* do share with *Curanderas* a commitment to service to their community and devotion to God, along with spirituality and a sense of mission. In contrast to many *Curanderas*, *Promotoras* exhibit active social involvement and leadership as a networker. A *Promotora* is a lay health educator who lives in the same community as members of the target population, speaks the language of the people she serves as well as the language of the dominant culture, and understands and is intrinsically involved in the host community. Effective *Promotoras* serve to bridge the gap between two cultures.

A crucial function of the *Promotora*, a peer health worker, in this project, and indeed when working among all indigenous and ethnic groups, is to educate while reinforcing the common identity shared by and with residents. This involves understanding and endorsing their shared traditional language, attitudes, values, and beliefs (8). In most projects that use this model, the peer health worker is a person selected from within the community and trained to do the following: 1) conduct health education classes in the community and 2) bridge the gap between the community and health care resources by providing referrals and, in some cases, by providing basic services to hard-to-reach populations in rural or urban settings. In the *Compañeros* project, the *Promotoras* were chosen from within their home churches.

From a systems perspective, the assumption underlying the *Compañeros* project is that the family, community, and church are of fundamental importance to Hispanic/Latino women.



Thus, for healthy behavior change to occur, a program must incorporate the family and the church community, while also attending to variations in traditional cultural values. In well-integrated, natural social systems, individuals may receive ample social support for dealing with health problems and other issues (9,10). In rapidly growing urban areas, such as those of the U.S. Southwest, however, such systems may not be in place. Thus, health promotion efforts must focus on engineering systems of social support for health behavior change (11-13). Developing a cadre of *Promotoras* constitutes one such support promotion effort.

## Methods

### Program Aims and Design

The target population consisted of Hispanic/Latino women aged 18 years or older, who attended a church of any denomination in the Phoenix metropolitan area. Monolingual Spanish-speaking (often low-acculturated), bilingual/bicultural, as well as monolingual English-speaking women were all eligible to participate. Since this was a church-wide intervention, non-Hispanic women were allowed to attend any of the *Compañeros* activities if they chose to do so.

**Basic design.** The basic design of the program had the following characteristics: 1) Churches served as the unit of analysis with 14 churches in Phoenix; 2) this experimental design involved the stratified randomization of churches to the experimental group (cancer control) or to the comparison group (family mental health); 3) a telephone survey sample of 40-100 women per church was chosen, depending on church size; and 4) all women who attended the participating church were eligible to attend any and all intervention activities.

**Experimental intervention: cancer control.** For the experimental group (cancer control), the intervention components consisted of the following: 1) classes on healthy eating, including information on high-fat, low-fat, and high-fiber foods; 2) healthy cooking demonstrations; 3) breast cancer information; 4) breast self-examination demonstrations and proficiency training; 5) cervical cancer information; 6) health fairs; and 7) arrangements to provide free clinical breast examinations followed by a referral to low-cost mammography and cervical examinations.

**Comparison group interventions: family mental health.** For the comparison group (family mental health), the intervention components were as follows: 1) classes on emotional well-being, including coping with stress (stress management) and coping with depression; 2) instruction for understanding family dynamics, along with an overview of acculturation and its effects on parent-child relations; 3) skills training regarding relaxation, assertion, and effective communications; and 4) examination of values, including discussions regarding cultural conflicts and acculturation and the promotion of family emotional health.

**The community.** The greater Phoenix metropolitan area has a population of more than two million, of which about 19.7% is Hispanic. Of the 280 000 Hispanics living in the Phoenix area, a total of 29 674 families (or approximately 178 000 persons) have rural roots and traditions and live at or below an income level of \$20 000 per year. The cohort that participated in the *Compañeros* project consisted of a subsample of 668 women who attended or were members of the 14 participating churches. These church congregations ranged from 40 Latino women to an estimated 3250 Latino women. One to three *Promotoras* were selected for each church. In this project, the *Promotoras* were considered to be volunteers, although they were each reimbursed \$500 per year for their expenses.

### Initiating Church Contacts

In the Phoenix area, the complement of 14 churches was recruited across a 9-month period during project year 01. Churches that had a significant Hispanic/Latino membership, i.e., 50% or more, were approached. This occurred before church randomization, thus establishing the need to inform all interested churches that they would be offered one of two health promotion programs that would be assigned "on a lottery basis." In this stage, the establishment of rapport with church leaders and the gradual development of a trustful relationship were

essential in the formation of a working partnership. In Latino cultures, this trustful working relationship is known as *confianza*. Earning the trust of the community is a gradual and fundamentally important condition for conducting health promotion that carries the endorsement of key community leaders, such as the priests, ministers, and lay leaders. Once earned, this *confianza* cannot be taken for granted; it must be nurtured and maintained.

### Base-line Survey

A base-line telephone survey was conducted to evaluate various aspects of health status, health behavior, health attitudes, acculturation status, and background information for a randomly selected sample of women from each of the churches. Membership rosters were obtained from each church, and the total size of the Hispanic female population by church was estimated. Given the large variability in church size, churches were classified into four strata: very large (1700 to 3500), large (800 to 1699), medium (150 to 799), and small (low to 149).

On the basis of these four church-size strata, individual women were selected randomly from church rosters to participate as survey respondents. Respondents were sampled in terms of "probability proportional to estimated size" (14). A minimum of 40 women were targeted for sampling from the smallest churches, and a maximum of 100 were targeted from the largest churches. Actual sample sizes by church ranged from 40 to 95 women, except for one small church that had a sample size of 19 women. The total sample size across the 14 churches was 668 Latino women.

More than 94% of participating women were interviewed by telephone. Women selected who did not have access to a telephone were interviewed in person at their church by a member of the *Compañeros* staff. The *Promotoras* were helpful in contacting these women and in arranging an interview time.

The base-line survey obtained initial data at the "pretest" observation, where a post-test was then conducted 1 year later to examine the influences of the *Compañeros* project on various measures of behavioral and psychological change. The base-line survey consisted of 10 sections that examined the following health areas: perceived health status; health insurance coverage; diet-related behavior; family history of cancer; fear of cancer; knowledge, attitudes, and behaviors related to breast or cervical cancer; religiosity; depression; family support for health; level of acculturation; and background information. The duration of this telephone survey ranged from 40 minutes to more than 1 hour. For slower respondents, two telephone sessions were conducted to reduce fatigue or to accommodate their wishes.

### Promotora Recruitment

The process of selecting *Promotoras* was initiated in interviews conducted first with priests/ministers and then with pastoral assistants and church secretaries. These individuals were asked to help identify women 1) who were actively involved in their community and had shown a commitment to the projects in which they were involved, 2) who showed leadership potential, and 3) who might have an interest in participating in the health promotion project. Women suggested by the church hierarchy were then contacted by telephone, and the project was briefly explained to them. A face-to-face interview was scheduled with them; at this interview, the project was explained to them in more detail. Women indicating an interest in the project were invited to help organize a focus group in the church.

Women were evaluated on their skills in scheduling and organizing the focus group. Furthermore, they were informally evaluated during the focus groups in terms of the respect given to them by women attending the meeting, the respect they demonstrated for others, their sensitivity to other women's concerns, their communication skills, and their expressed interest in the subject of health education. Women who remained interested in the project and who exhibited aptitudes relevant to being a *Promotora* were invited to a second meeting, at which the project was described to them in more detail and the role of the *Promotoras* carefully outlined, the time commitment involved, and the remuneration that was available. On average, of the 10-15 women attending each focus group, four attended this class, and two, mainly those who had time for the project, were chosen to be *Promotoras*.



## Results

Base-line survey data were used to compile a profile of characteristics for churches, the *Promotoras*, and the participants. Also, participant psychosocial characteristics were analyzed in relation to the four levels of church size (i.e., very large, large, medium, and small).

### Characteristics of Churches, *Promotoras*, and Participants

Table 1 shows a macro-level descriptive analysis of the 14 participating churches, along with general characteristics of the *Promotoras* and of participants by church. Churches had been stratified by size on the basis of the estimated number of Latino women identified as church members from church rosters.

**Church characteristics and patterns.** The larger churches (very large, large, and medium) were almost exclusively Catholic, while the small churches were almost exclusively Protestant (Table 1). This appears to be a naturally occurring pattern within the local community.

***Promotora* characteristics.** The *Promotoras* who participated in the *Compañeros* project ranged in age from 27 to 67 years. There was no consistent pattern among the *Promotoras* in terms of being younger or older than the average for the women of the congregation whom they served. Regarding *Promotora* income relative to the income of the women they served, six *Promotoras* had higher income, three had lower income, and two had similar incomes. Thus, there was a slight tendency for the *Promotoras* to have a somewhat higher income than the

**Table 1.** Demographic characteristics of churches, *Promotoras*, and participants

Size strata (name)	Church					<i>Promotoras</i>			Participants				
	% Hispanic	Estimated Hispanic women	Intervention*	Denomination	Neighborhood†	Age, mean (SD)‡	Household income, mean (SD)‡,§	Acculturation, mean (SD)‡,	Age, mean (SD)	Household income, mean (SD)§	Acculturation, mean (SD)	Marital status, %¶	Distance from church, miles, mean (SD)
Very large (1700-3500)													
Church (QP)	65	3250	C	Catholic	UM-UR	48.33 (11.02)	6.00 (1.73)	2.93 (0.17)	42.45 (14.50)	5.96 (2.13)	3.38 (0.91)	69.23	2.55 (0.97)
Church (St. C)	59	1700	F	Catholic	LO-IN	48.50 (13.44)	4.50 (0.71)	2.33 (0.58)	42.41 (12.28)	6.62 (1.58)	3.35 (0.88)	85.37	2.29 (0.84)
Large (800-1699)													
Church (St. A)	45	800	C	Catholic	M1-UR	48.00 —	8.00 —	3.00 —	41.79 (11.18)	6.29 (2.11)	3.68 (0.76)	75.86	2.06 (1.00)
Church (PIM)	100	800	C	Methodist	LO-IN	38.33 (5.03)	7.00 (1.73)	2.37 (1.01)	43.52 (14.48)	5.17 (2.13)	2.72 (0.92)	64.91	2.53 (1.32)
Church (IH)	95	1600	F	Catholic	LO-IN	33.00 (12.73)	8.00 —	2.60 (0.28)	47.83 (13.84)	5.33 (2.34)	3.07 (0.91)	61.36	3.02 (1.04)
Church (St. D)	50	1200	C	Catholic	M1-UR	31.00 —	6.00 —	2.40 —	41.32 (16.45)	5.48 (2.16)	2.98 (0.96)	75.00	2.34 (0.94)
Medium (150-799)													
Church (St. Mk)	80	350	C	Catholic	LO-UR	67.00 —	7.00 —	3.20 —	44.93 (16.07)	5.37 (1.99)	3.09 (0.93)	80.36	1.80 (1.08)
Church (St. Mt)	95	160	F	Catholic	LO-RU	56.00 (11.43)	5.00 (1.41)	2.35 (1.01)	48.71 (11.43)	5.90 (2.20)	2.89 (1.00)	64.52	2.23 (1.02)
Small (low to 149)													
Church (IP)	100	70	C	Presbyterian	LO-UR	27.00 —	3.00 —	1.60 —	51.54 (15.91)	5.92 (2.17)	3.14 (0.91)	70.37	3.19 (0.97)
Church (NV)	100	104	C	Church of God	UM-UR	45.00 —	—	1.80 —	31.11 (10.74)	5.35 (1.83)	2.34 (0.66)	68.18	3.34 (0.89)
Church (SP)	100	65	F	Episcopal	LO-IN	27.00 (7.07)	8.00 —	1.70 (0.14)	36.89 (11.46)	4.86 (2.21)	2.49 (0.79)	55.26	2.58 (1.25)
Church (St. Ma)	100	149	F	Catholic	M1-UR	48.00 —	7.00 —	2.50 —	42.35 (13.49)	4.61 (2.04)	2.65 (0.80)	76.47	2.38 (1.04)
Church (CF)	100	40	F	Protestant	M1-UR	45.50 (4.95)	8.00 —	3.20 (0.28)	37.22 (11.01)	5.38 (1.98)	2.47 (0.79)	77.78	3.17 (0.86)
Church (SA)	100	50	C	Protestant	LM-UR	27.00 —	5.00 —	2.00 —	42.19 (21.07)	3.75 (1.65)	2.28 (0.67)	53.85	2.88 (1.24)

\*C = cancer risk reduction (experimental group); F = family mental health (control group).

†Social class: LO = lower class; LM = lower middle class; M1 = middle class; UM = upper middle class. Location: RU = rural; SU = suburban; UR = urban; IN = inner city. Thus (LO-IN) would mean lower class, inner city.

‡The — symbol for standard deviation values for *Promotora* characteristics indicates no variance because that church had only one *Promotora*. For household income only, a — symbol for a mean value indicates that the *Promotora* could not or did not provide this information.

§Income categories are 1 = ≤\$250; 2 = \$251-\$500; 3 = \$501-\$750; 4 = \$751-\$1000; 5 = \$1001-\$1250; 6 = \$1251-\$1500; 7 = \$1501-\$1750; 8 = ≥\$1751.

||Acculturation is measured on a scale from 1 to 5 in which scores from 1.0 to 2.39 indicate low level of acculturation, scores from 2.40 to 3.69 indicate bilingual/bicultural, and scores from 3.7 to 5.0 indicate high level of acculturation. Low acculturation refers to Spanish-speaking, Hispanic/Latino culture oriented, while high acculturation refers to English-speaking, Anglo-American culture oriented. Bilingual/bicultural refers to having linguistic skills and orientation to both cultures.

¶Marital status refers to percent married.

mean income of the women they served. Regarding level of acculturation, nine *Promotoras* had a level of acculturation lower than that of the women whom they served. Only one *Promotora* had a higher level of acculturation, and two had a similar level. Thus, the *Promotoras* as a group had a level of acculturation lower than the mean level among the women of their congregation.

**Participant characteristics.** For participants (church members), differences by church size were also observed for the major background variables of age, income, level of acculturation, and distance living from their church. Generally, women from the small churches were younger, poorer, and less acculturated and lived farther away from their church, as shown by the one-way analysis-of-variance tests on these variables (Table 2).

For the entire sample of participants, the level of acculturation was correlated significantly with income ( $r = .49$ ;  $P < .001$ ). Thus, the more acculturated women tended to have higher incomes. Age was only slightly related to income ( $r = -.10$ ), and age was only slightly related to level of acculturation ( $r = .09$ ). Given these results, age and level of acculturation were observed as important covariates in relation to church size. Thus, for parametric variables, a one-way analysis of covariance, with age and acculturation as covariates, was used to examine psychosocial variables in relation to church size. For non-parametric variables, a Cochran-Mantel-Haenszel chi-squared test was used, in which age adjustment involved stratification by age level ( $\geq 40$  years or  $< 40$  years) and by acculturation (a score of  $\geq 3.00$  or  $< 3.00$ ) (15).

### Participant Characteristics by Church Size

Table 2 also presents psychosocial characteristics of the participating women as stratified by the size of the church that they attended. With regard to health background, these women did not differ in their self-rating of health, which was rated as a bit less than "good." These churches did not differ in the proportion of Latino women who had ever smoked cigarettes (between 31% and 37%) or in the proportion of Latino women who had a close relative who had had cancer (between 33% and 47%). By contrast, these churches did differ in the proportion of women who had health insurance. The larger churches had higher proportions of women who had health insurance (very large churches, 69.81%; large churches, 63.18%) than the smaller churches (medium churches, 55.81%; small churches, 51.40%;  $\chi^2 = 12.19$ ;  $P < .05$ ).

With regard to base-line measures relevant to breast cancer, women within these churches who had obtained a clinical breast examination and those who had obtained a mammogram did not differ in the period of time since their last examination. Also, for women older than age 40 years, there were no differences by church size in the percentage of women who had ever received a mammogram; more than 69% of women had ever received a mammogram across all four church groupings. However, differences across churches by church size were observed in regard to the proportion of women who had ever received a clinical breast examination (ranges between 93% and 27%;  $\chi^2 = 13.75$ ;  $P < .01$ ). A remarkably low percentage (27.08%) was observed for the small, primarily Protestant churches with regard to

lifetime rates of having had a clinical breast examination, relative to the very large, large, and medium churches, whose participating members had lifetime clinical breast examination rates of 92.45%, 89.04%, and 88.37%, respectively. One-way analysis-of-covariance tests of the dietary and psychological variables, when adjusted for age and level of acculturation, revealed no differences by church size. Unadjusted differences that were significant across church size on the variables of low-caloric/high-fiber and fear of cancer disappeared after adjustments for age and acculturation.

## Discussion

### Church Cohesiveness: Implications for Program Development

The results of analyses from the base-line survey that were conducted across churches, *Promotoras*, and participants revealed some naturally occurring patterns that covaried by church denomination and size. The larger churches were primarily Catholic, and the smaller churches were primarily Protestant. This is a natural extension of the nearly 500 years of predominance of Catholicism in Latin American, with Protestant evangelism (primarily of U.S. origins) a recent and still relatively small phenomenon. Thus, relative to the newly emerging and still small, Protestant churches, Catholic churches have developed as large social systems among Latinos. This outcome suggests the need for a different approach toward health promotion in working with large, Catholic churches as opposed to the small, Protestant churches.

Besides differences in religious belief, the larger churches also require greater effort in coordinating initial contacts with a larger number of influential members during the program initiation stage. Whether larger churches have a higher or lower level of cohesiveness involving social bonding and personal involvement in church activities is not clear. However, as cohesion and involvement increase within a given church, so should successful diffusion of a health promotion innovation, as members communicate among themselves regarding the activities of the health promotion program. By contrast, a fragmented, low-cohesion church, in which social bonding and member involvement are low, should exhibit communication gaps and interpersonal barriers to the diffusion of health promotion innovations. Such gaps in communication and diffusion, if significant, could constitute a barrier to the initiation, implementation, and institutionalization of a health promotion program within such a church. Larger "mainstream" churches in which memberships may be relatively automatic (e.g., as a result of residence in a parish) rather than requiring personal commitment may be prone to such fragmentation compared with smaller churches.

Another pattern observed in the base-line data is that women within the Protestant churches relative to the women within the Catholic churches were younger, had lower incomes, were less acculturated, and lived somewhat further away from their church. Living at a greater distance from the church might reduce regular participation in church activities that are conducted after church services and/or at times between church services. As one example, one inner city *Compañeros* church in which members rarely stayed around to visit after the church



Table 2. Participant psychosocial characteristics by church size\*

Characteristic	Church size				Test of significance†
	Very large, mean (SD)	Large, mean (SD)	Medium, mean (SD)	Small, mean (SD)	
Age, y	43.44 (13.62)	43.35 (13.58)	46.28 (14.63)	40.97 (15.90)	$F_{3, 618} = 2.90, P < .05$ S < M
Household income	6.20 (1.96)	5.72 (2.21)	5.54 (2.05)	5.08 (2.11)	$F_{3, 434} = 4.99, P < .01$ S < VL
Acculturation	3.37 (0.90)	3.21 (0.95)	3.02 (0.95)	2.62 (0.84)	$F_{3, 623} = 22.15, P < .001$ S < M, L, VL; M < VL
% in married	75.47	70.00	74.71	66.82	$\chi^2 = 3.42, NS$
Distance from church in miles	2.45 (0.93)	2.41 (1.14)	1.95 (1.07)	2.95 (1.09)	$F_{3, 614} = 19.69, P < .001$ S > M, L, VL; M < L, VL
Health background					
Self-rating of health	2.72 (0.73)	2.68 (0.73)	2.70 (0.73)	2.71 (0.74)	$F_{3, 615} = 0.12, NS$
Ever smoked cigarettes, %	34.91	36.82	35.63	30.99	$\chi^2 = 1.74, NS$ $\chi^2_{CMH} = 1.88, NS$
Have health insurance, %	69.81	63.18	55.81	51.40	$\chi^2 = 12.19, P < .01$
Family member ever had cancer, %	46.67	45.00	33.33	38.50	$\chi^2 = 5.45, NS$
Breast cancer					
Clinical breast examination (ever), %	92.45	89.04	88.37	27.08	$\chi^2 = 13.75, P < .01$
Mammography (ever), for women over age 40, %	80.00	76.23	69.81	70.65	$\chi^2 = 2.37, NS$ $\chi^2_{CMH} = 4.23, NS$
Mammography (last)	1.35 (0.74)	1.41 (0.73)	1.30 (0.73)	1.41 (0.74)	$F_{3, 313} = 0.58, NS$
Clinical breast examination (last)	1.35 (0.72)	1.36 (0.72)	1.27 (0.71)	1.30 (0.74)	$F_{3, 532} = 0.26, NS$
Cervical cancer					
Cervical examination (ever), %	97.17	95.87	94.19	88.21	$\chi^2 = 13.65, P < .01$ $\chi^2_{CMH} = 5.11, NS$
Cervical examination (last)	1.38 (0.85)	1.44 (0.85)	1.27 (0.84)	1.51 (0.86)	$F_{3, 567} = 1.61, NS$
Diet					
Low-caloric/high-fiber	19.01 (8.13)	17.72 (8.11)	17.62 (8.02)	16.55 (8.27)	$F_{3, 616} = 2.11, NS$
High-caloric/high-cholesterol	7.31 (4.89)	7.91 (4.88)	6.69 (4.82)	6.73 (4.98)	$F_{3, 615} = 2.47, NS$
Psychological					
Depression	0.25 (0.31)	0.25 (0.31)	0.28 (0.30)	0.23 (0.31)	$F_{3, 616} = 0.57, NS$
Fear of cancer	2.41 (0.50)	2.45 (0.50)	2.37 (0.50)	2.44 (0.51)	$F_{3, 616} = 0.66, NS$
Faith in Supreme Being	3.36 (0.62)	3.26 (0.62)	3.35 (0.61)	3.22 (0.63)	$F_{3, 607} = 1.61, NS$
Satisfaction with self	3.87 (0.56)	3.84 (0.55)	3.90 (0.55)	3.89 (0.57)	$F_{3, 616} = 0.38, NS$
Support from spouse/family	3.71 (1.05)	3.79 (1.05)	3.67 (1.04)	3.74 (1.07)	$F_{3, 615} = 0.35, NS$

\*See footnotes to Table 1 for explanation of household income and acculturation. Self-rating of health: Is a single item that is measured on a dimension of 1 = poor, 2 = fair, 3 = good, and 4 = excellent. Mammography (last): Is a single item that is measured as a period of time on a dimension of 1 = within the past 0-12 months, 2 = within the past 13-24 months, 3 = within the past 25-60 months, and 4 = >60 months. Clinical breast examination (last) and cervical examination (last): Is a single item measured as a period of time on a dimension of 1 = within the past 0-12 months, 2 = within the past 13-24 months, 3 = within the past 25-60 months, and 4 = >60 months. Low-caloric/high-fiber: Is a six-item index of behavior frequency that measures frequency in the past week in the consumption of a serving or unit of food items, i.e., the consumption of a salad or raw vegetable; a fruit; whole grain breads or cereals; lean white meat; or a dark green, leafy vegetable. High-caloric/high-cholesterol is a seven-item index of behavior frequency that measures frequency in the past week in the consumption of a serving or unit of food items, i.e., the consumption of butter; red meat; sugar drink, soda; sweet snack; a pastry; ice cream; or food cooked in lard. Depression: Is a 20-item symptom frequency scale of how often during the past week the person felt any of 20 depressive symptoms on a dimension of 1 = <1 day (rarely or none of the time), 2 = 1-2 days, 3 = 3-4 days, and 4 = 5-7 days. Fear of cancer: Is a scale of five items, each of which is measured on a dimension of 1 = strongly disagree, 2 = disagree, 3 = not sure, 4 = agree, and 5 = strongly agree. Faith in a Supreme Being: Is a single item that is measured on a dimension of 1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree. Satisfaction with self: Is a five-item scale that is measured on a dimension of 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied. Support from spouse/family: Is an eight-item scale that examines level of support from others for own health that is measured on a dimension of 1 = never, 2 = seldom, 3 = sometimes, 4 = often, and 5 = always.

†NS = not significant;  $\chi^2_{CMH}$  = Cochran-Mantel-Haenszel chi-squared test; VL = very large; L = large; M = medium; S = small.

service developed the reputation of being a "commuter church." In this church, many members had moved away from the church neighborhood but had maintained membership because of multi-generational ties with that church. The average distance that members lived from that church was more than 3 miles. Moreover, many members apparently had not developed an emotional or social bonding with other church members, despite sincere and conscientious efforts by the pastor to create such bonding. This highly fragmented church became a system in which it was difficult to induce participation in various *Compañeros* activities. Whether distance from the church or other social, interpersonal, normative, or historical factors operated to create this fragmentation is an area for additional study.

### Participant Need for *Promotora* Aid Relative to Church Size

The very large and large churches relative to the medium and small churches had relatively higher proportions of women who had health insurance. This outcome has implications with regard to access to screening and health services. The women from the smaller, Protestant churches needed more auxiliary aid from the *Promotora*, given their lower rates of health insurance coverage, their lower incomes, and their lower levels of acculturation. Being uninsured and poor and speaking only Spanish constitute conditions of greater need for the services of a *Promotora*.

This greater need for *Promotora* services was also partially suggested by data on screening behavior. The women from the smaller, Protestant churches exhibited lower rates of ever having received a clinical breast examination. By implication, the Latino women from the smaller, Protestant churches might be at a relatively greater risk of having undiagnosed cancer.

### Cultural Sensitivity in Working With Churches

In any community, churches will vary considerably in size, their institutional history, the cohesiveness of the congregation, and the congregation's preparedness to adopt and participate in a program that promotes healthy behavior change. Mobilizing churches to participate in a health promotion partnership requires careful attention to these and other church characteristics. Attention to these characteristics is important in efforts to formulate a working partnership that is tailored to the unique needs and characteristics of each church. In Latino/Hispanic cultures, this personalized approach, known as *personalismo*, is most important. In addition, the development of this partnership evolves from a consistent effort to develop trust and confidence in the skills and motives of the health promotion team, and this trust typically evolves slowly (16). This trust, known in the Latino cultures as *confianza*, must be earned. In the *Compañeros* project, a period of about 9 months was required to recruit and enlist our participating group of churches, and continued contact and nurturance were necessary.

The observed naturally occurring patterns of church and participant characteristics and the related need for *Promotora* services underscore the importance of recognizing the broad variability that exists among churches within a given community. Ostensibly, these differences suggest differential approaches for effective health promotion in relation to church structural characteristics that, in turn, influence the behavioral

dynamics of church members (17). A more in-depth, naturalistic, ethnographic observation of the dynamics of church member behavior as influenced by church structural characteristics would further clarify the initial observations presented in this article.

Beyond this analysis of participant need by church size, a compelling and unresolved issue in cancer health promotion with indigent populations involves program limitations in procuring affordable treatment for women diagnosed with breast cancer. The dilemma is that, in the long-run, screening may provoke fear and anxiety as cases emerge for which treatment is needed but not available to impoverished and uninsured Latino women. The ethical issue concerns the advisability of screening if sources of affordable treatment are not available. On the one hand, if not screened, many Latino women will not be diagnosed at sufficiently early stages to obtain effective and less aggressive treatment. On the other hand, detecting cancer, at whatever stage, in the absence of available treatment introduces a painful discovery that cannot be remedied because of a lack of insurance and financial resources. The ethical issues surrounding screening for breast cancer among indigent women requires further discussion.

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## Notes

<sup>1</sup>The literature on Latino health has no consensus regarding the preferred term to use when referring to persons of Latin American heritage who live in the United States. The terms "Hispanic" and "Latino" are both used extensively, al-

though U.S. Government documents use the term "Hispanic." Given this mixed usage in the present literature, this article will use the terms "Latino" and "Hispanic" interchangeably.

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# Por La Vida Intervention Model for Cancer Prevention in Latinas

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Our goal was to describe the development and implementation of an intervention on cancer prevention for Latinas in San Diego, Calif. Thirty-six lay community workers ("consejeras") were recruited and trained to conduct educational group sessions. Each consejera recruited approximately 14 peers from the community to participate in the program (total number = 512). Half of the consejeras were randomly assigned to a control group, in which they participated in an equally engaging program entitled "Community Living Skills." Implementation of the intervention was assessed by qualitative and quantitative methods. Preintervention and postintervention self-report information was obtained from project participants on access to health care services, cancer knowledge, preventive measures, and previous cancer-screening examinations. Base-line data suggest that lack of knowledge, costs of cancer-screening tests, and the lack of a regular health care provider are the major obstacles against obtaining cancer-screening tests. Predisposing factors, such as fear and embarrassment, also constitute barriers to getting regular cervical cancer screening. Preliminary analysis indicates that the *Por La Vida* intervention increases use of cancer-screening tests in comparison to a community living skills control group. Universal access to health care would remove some of the major financial barriers to cancer screening. The *Por La Vida* program attempts to overcome the substantial barriers by reaching out to low-income Latinas and by providing information regarding the availability, acceptability, and preventive nature of cancer-screening tests. [Monogr Natl Cancer Inst 18:137-145, 1995]

Meeting the Healthy People 2000 objectives for breast and cervical cancer reduction may be particularly challenging for Latinas. For example, the proportion of women older than 50 years who have received a clinical breast examination and a mammogram within the past 2 years must increase from 18% to 60%, while the percentage of women 40 years old or older who have ever received these examinations must increase from 20% to 80% (1). Although challenging, these are worthy goals. Mortality due to breast cancer can be reduced by 30% if women obtain regular mammography and clinical breast examinations (1). Moreover, invasive cervical cancer is almost totally preventable by early detection of malignancy at the in situ stage through screening with the Pap test (2).

Recent data also indicate that progress has been made toward the accomplishment of the health objectives for the year 2000.

Data from the cancer 1987 and 1990 National Health Interview Surveys suggest that the proportion of women older than 40 years of age who used mammography almost doubled between 1987 and 1990 (from 17% to 33%) (3). While ethnic differences declined in the 1990 survey, income and education remained strong predictors of screening. The National Health Interview Survey also sheds light on some of the reasons why eligible women did not receive a mammography examination. The most frequent reasons were the lack of knowledge about mammography and recommended frequency (mentioned by 41.2% of the respondents) and the lack of a physician's recommendation (30.7%). Cost was mentioned as a barrier by 7.2% of the respondents (3).

## Breast and Cervical Cancers in the State of California and in San Diego, Calif.

In California, it is estimated that approximately 20 000 and 6000 new cases of breast and uterine cancers, respectively, will be diagnosed in 1994 (2). Three-year incidence counts between 1988 and 1990 indicate that the most common cancers among Latinas are breast cancer (3831) and cervical cancer (1305). Furthermore, 54% of the breast cancers diagnosed among Latinas in California between 1988 and 1990 were detected at an early stage (in situ and local) as compared with 66% of the cancers detected early among non-Latina whites. The proportion of cervical cancers detected at early stages among Latinas in California was 87%, while 90% of cervical cancers were detected early in the non-Latina white population. In San Diego, the differences between Latinas and non-Latina whites were more pronounced, with 76% and 90% of cervical cancer detected early, respectively (2).

Differences between ethnic groups regarding the proportion of breast and cervical cancers diagnosed at early stages can be partly explained by differences in cancer-screening practices.

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See "Note" section following "References."



Data from the 1991-1992 Behavioral Risk Factor Survey (2) in California indicate that among women 50 years of age or older, white non-Latinas were more likely to report having had a mammogram within the past 2 years (73%) and Latinas were the least likely to report having had one (61%) in the past 2 years. With regard to cervical cancer, 91% of nonhysterectomized California women reported having had at least one Pap test and 70% reported having had one within the past year. The percentage of women who had had a Pap test during the last year was highest among African-American women (83%), followed by whites (74%), Latinas (61%), and women of other race/ethnicity (59%) (2).

## **The Latino Population in the State of California and in San Diego, Calif.**

In California, 25.8% of the population is Latino (4). Latino fertility has been climbing steadily since 1974, and immigration from Mexico and Latin America has increased considerably since 1970. If current fertility and immigration trends continue, by the year 2000 the largest non-Anglo group in California will be Latino, making up about 33% of the population in the state (5).

The great majority (80%) of the Latino population in California is of Mexican origin. In an analysis of current migration trends, Cornelius (6) pointed out that one of the constants in the profile of Mexican migration to the United States in recent decades is the leading role of California as a destination. The 1978 national survey of households in Mexico by Centro Nacional de Informacion y Estadisticas del Trabajo (6) found that California was the destination of 47.3% of Mexican migrants to the United States. The Immigration and Naturalization Services statistics show that, since the 1970s, California has absorbed about half of the total flow of legal immigrants from Mexico. Moreover, in recent years, San Diego has been one of the 10 metropolitan areas receiving the most legal Mexican immigrants (6).

In San Diego County, more than half a million of the population is Latino, and 85.9% of the Latinos in San Diego are of Mexican origin (4). The Latino population showed a dramatic increase in its representation, growing from 14.8% of the total in 1980 to 20.4% in 1990. Data from the 1990 census published by the Sourcepoint Corporation (7) indicate that, numerically, the Latino population grew at a rate substantially higher than that of the San Diego region as a whole (85.6% and 34.2%, respectively). The growth of the Latino population in San Diego also surpassed California's percentage growth. California's Latino population expanded by 3.1 million people or just over 69% (7).

In 1990, Latinos in California had the highest percentage (22.1%) of families living in poverty of any ethnic/racial group (5). On the basis of the 1980 census, Chávez (8) found that, compared with San Diego's other major population groups, including other Latinos, Mexican immigrants are less educated, earn less money, and live in households with more individuals.

Moreover, important differences exist between ethnic groups with regard to access to medical care. For instance, in 1992, the National Council of La Raza (9) published a report concluding that Latinos with lower incomes are much more likely than Latinos with higher incomes to be uninsured, and Latinos are

less likely than non-Latino whites to be covered by health insurance at every income level. It is estimated that approximately 40% of Mexican-Americans are uninsured in the United States (10), and 37% of the Latino population in California lack health insurance (9). The 1982-1984 Hispanic Health and Nutrition Examination Survey (HHANES) also provides information about access to health care services among Hispanics. Low-income groups, younger groups, the less acculturated, and those who lack health insurance coverage encounter more barriers to health care services than others and are prevented by these barriers from obtaining health care for themselves (11). In addition, with regard to the use of preventive services, results of the HHANES suggest that, among Latinos, having a routine place for health care, health insurance coverage, and a regular health care provider each was significantly associated with greater recency of screening (12).

In summary, data from a variety of sources suggest that many members of the Latino community have limited access to health care services and are in need of health promotion services. In order to address these problems, we have developed a health promotion program specifically targeted at the Latino community in San Diego. In particular, our intervention targets the San Diego Latino community of low socioeconomic level and low level of acculturation. The theoretical framework for the program is presented in the following section.

## **Theoretical Framework**

Our interventions are based on a cognitive social learning theory (13). The theory suggests that the performance of learned behaviors is contingent on the expectation of reward or punishment. The social learning theory differs from traditional learning models, which require that behaviors are conditioned through direct reinforcement. Thus, according to the most traditional views, a woman would acquire the behavior of obtaining a mammogram if she was rewarded for the activity. The longer the latency between the behavior and the reinforcement, the weaker the acquired behavior. The social learning theory suggests that behaviors can be learned through information and vicarious process. Women can learn about the negative consequences of breast cancer from the experiences of others, and they can also learn that activities such as cancer screening may offer protection. Performance of the behavior (obtaining a cancer-screening test) is contingent on whether the activity is *expected* to lead to reward or punishment.

Early studies of the social learning theory suggested that characteristics of models who impart the information are important. For example, similarity between models and learners in terms of age, sex, and ethnicity is associated with a more efficient learning process (14). The self-efficacy theory, a more recent formulation of the social learning theory, suggests that the performance of behavior is based on two related expectations: outcome expectations and efficacy expectations. Outcome expectations are beliefs that a particular behavior will lead to a defined outcome. For example, the belief that obtaining a Pap smear reduces the risk of cervical cancer is an outcome expectation. Efficacy expectations refer to the beliefs that the required behaviors can be performed. A woman may know that Pap



smears are beneficial (outcome expectation) but may not have confidence that she can find the right provider, ask the right questions, or obtain the financial resources to complete the test. Performance of the behavior requires both outcome and efficacy expectations.

Community health promotion programs have been shown to be effective among middle-income, majority populations (15,16); however, programs targeting Latinos have been limited until recently (17-20). Our review of the literature identified a variety of reasons why successful health programs among middle-income, majority populations have fallen short of their potential impact with Latinos. These reasons include problems related to the following issues: disease perception, cultural similarity, social networks, language of materials, and child care. Each of these issues will be addressed separately.

### **Disease Perception**

Expectation is a central tenet of the social learning theory. Performance of a behavior is contingent on the expectation that the behavior will lead to the desired outcome. In the self-efficacy theory, this is the construct of outcome expectation. Little research attention has been devoted to the determinants of cancer-screening test use or to the outcome expectations of Latina women. It has been suggested that Latinas' perceptions of cancer range from fatalistic, to the attribution of cancer to lifestyle and environmental factors, to divine punishment for bad deeds of the patient or family member (21-23). Health education programs do not always spend the necessary time and energy understanding target population expectations through, for instance, the use of focus groups before developing interventions (24).

### **Cultural Similarity**

The social learning theory suggests that new behaviors are most successfully learned and performed if they are demonstrated by a model who is similar in age, sex, and ethnicity (14). Traditional health education methods that use ethnically dissimilar instructors have not tended to be successful (25). It has been noted that recent immigrants to the United States tend to be in better health and that higher levels of acculturation are associated with poorer health status (26,27). Health promotion programs that have been developed for Latinos often fail to address positive cultural attributes that may enhance their effectiveness. These attributes include the following: interdependence, affiliation (including strong ties to community norms of family, hard work, and responsibility to the neighborhood), cooperation, and total family involvement with major decisions (24,28). The role of the Latina in family betterment is often overlooked as a key source of social reinforcement.

### **Social Networks**

Only recently have health promotion programs recognized the need to work through the naturally occurring social networks that exist in the Latino community (29-31). According to the social learning theory, supportive peers reinforce the expectation that treatment will produce benefit. The self-efficacy theory suggests that the most effective methods to produce behavior change are through participant modeling and vicarious ex-

perience with similar individuals. For example, a behavior may be most effectively learned if a woman succeeds at it herself or if she witnesses the successful execution of the behavior by a person similar to her. Naturally occurring social networks capitalize on the established levels of trust among similar peers.

Evidence is accumulating that, especially in the Latino community, the use of link persons, "consejeras" or "promotoras," to disseminate culturally appropriate information facilitates effective communication. These link persons are generally women from the community who were identified as playing the traditional role of care giver or adviser in Latino culture (32). Models from outside the community may face difficulties in the implementation of any health promotion program.

In addition to these theoretical issues, several practical considerations must be considered. These include the language of the instructional materials and the need for child care.

### **Language of Instructional Materials**

One way to meet the needs of Latinos for increased access to health care is to provide intensive health educational programs conducted by community groups and particularly the preparation and dissemination of preventive health materials in Spanish (33). Until recently, most educational efforts relied on the translation of English materials into Spanish, rather than the development of culturally and linguistically specific materials for the Latino community. This practice, in addition to the general lack of Spanish language materials, posed a serious barrier to effective program implementation.

### **Need for Child Care**

A final concern is the failure to recognize the importance of providing child care during any educational session. Lack of child care may contribute to high dropout rates. Child care works as a valuable incentive and removes an important barrier to attendance.

In order to address these problems, we have developed and evaluated a new intervention model that works with the assets of the Latino community. The model is presented in the next section.

## **Development of the Intervention Following the *Por La Vida* Model**

### **The *Por La Vida* Model**

Since 1988, three separate health promotion programs have been conducted in San Diego following the *Por La Vida* (i.e., For Life) intervention model. These programs have specifically targeted the low-socioeconomic-level Latino community in San Diego. The complete *Por La Vida* model evolved over several years and is characterized by the following process:

- 1) Women from the Latino community are identified as *consejeras* on the basis of their leadership behaviors associated with the traditional role of "helpers" in the Latino community.

- 2) These women are recruited as *consejeras* and are subsequently trained to conduct small-group educational sessions on a particular health topic.



3) Upon completion of the training, the consejeras invite women to participate in the small group from their naturally occurring social networks, i.e., women who are friends, neighbors, or family members.

4) The consejeras conduct small-group sessions using culturally appropriate educational materials developed by *Por La Vida* staff in collaboration with the community. The materials are always printed in both English and Spanish, side by side, and have a reading level equivalent to a 6th or 7th grade education. The sessions are conducted in such a way as to minimize the need for reading skills and are based on empowerment strategies, social support, and social learning theory principles of modeling, change in small steps, and skills training.

5) The program is followed by a "graduation day" with a potluck meal and certificates of completion bestowed on the participants by their consejeras.

In addition, child care is provided for all educational sessions and is essential for project attendance and success. All educational sessions are conducted in community sites, such as schools, recreation centers, community centers, and churches. The sites as well as the time at which the sessions take place are determined by each consejera and her group participants in coordination with project staff.

Community ownership is promoted throughout the program. Community members are an integral part of the development of strategies, educational themes, physical sites, and the content, colors, and activities incorporated into the educational materials. Even the name *Por La Vida*, the logo, and program identifiers were all determined by community members.

In the following section, we report evidence from qualitative and quantitative studies that supports the rationale for the *Por La Vida* program. In addition, preliminary evidence on the effectiveness of the program will be presented.

## Qualitative Study

Twelve focus groups, involving 86 participants, were conducted to identify barriers to the use of cancer-screening tests. Six of the groups were with health care providers, and six included Latino community women. Both Latinas and providers emphasized lack of knowledge and cultural issues as barriers to the use of cancer-screening tests. While the women spent most of their time addressing these issues, the providers discussed them only briefly. The providers concentrated more on lack of health insurance and on characteristics of the clinics, costs, and provider attributes. These problems were rarely mentioned by the women, who were more likely to describe the barriers as social and environmental. Both the women and the providers noted that physicians rarely recommend screening tests (34). Thus, the qualitative study points to important barriers and reinforces the need to involve community peers in the communication of information about cancer screening.

## Intervention for Cancer Prevention

Taking into account information from the focus groups, the *Por La Vida* intervention program for cancer prevention was developed. The program consists of 12 weekly group sessions conducted over a 3-month period. Two additional sessions are offered in the months following graduation within a year from

the beginning of the group meetings. The purpose of the additional sessions is to reinforce long-term learning of materials and to keep in contact with program participants to facilitate completion of follow-up measures. Table 1 lists the content of the 12 weekly educational sessions as well as the additional booster sessions. Each of the sessions lasts approximately 90 minutes. A manual for consejeras was developed that includes educational objectives, materials needed, and outlines of the relevant activities for each session. Throughout the program, *Por La Vida* staff provides to consejeras pamphlets, work sheets for participants, posters, plastic models of the female body, and pelvic models. The manual for the consejeras and pertinent work sheets for project participants were developed in Spanish and translated to English by *Por La Vida* bilingual and bicultural staff with feedback from the target community throughout the development process. In addition to *Por La Vida's* newly developed educational materials, we also distribute to program participants information pamphlets available from other organizations, particularly from the National Cancer Institute and the American Cancer Society.

## Methods

### Subjects

Participants were recruited through the consejeras. A total of 512 Latinas were initially recruited to participate in their respective groups. On average, there were 14 participants per group. However, the number of regular program participants at the end of the educational sessions exceeded 600. In addition, more than 100 women participated occasionally in the educational sessions invited by regular program participants.

Major sociodemographic characteristics of the participants are summarized in Table 2. The average age of the participant was 34 years (range, 18-72 years). The median years of formal education was 7, and the median yearly gross family income was \$12 000. The average family size was five persons. The majority of the women were married and full-time homemakers. Ninety-two percent of the interviewees were born in Mexico, 5% in the United States, and 3% in other Spanish-speaking countries. Women not born in the United States had been living in this country approximately 8 years on average. The average acculturation, as measured by the Marín's Short Scale of Acculturation (35) (range: 1 [low level] to 5 [high level] of acculturation), was 2. Ninety-seven percent of the participants preferred to be interviewed in Spanish. These results emphasize the

**Table 1.** Topics of the *Por La Vida* educational sessions for cancer prevention

Weekly session No.	Topic of weekly sessions
1	Introduction
2	The Fountain of My Life
3	The Feminine Body
4	Where Cancer Can Be Found
5	Keeping Your Uterus and Cervix Healthy
6	Keeping Your Breasts Healthy
7	Overcoming Barriers
8	Eat Well to Live Well
9	Protect Your Health, Know Your Market
10	Dangers of Smoking
11	Moving Ahead
12	Graduation
Topic of additional sessions	
Ask the Doctor	
Menopause	



**Table 2.** Sociodemographic characteristics of the *Por La Vida* participants (n = 512)\*

Variable	Median	Group (%)
Age	34 y	<40 y (69.1) 40-49 y (20.9) ≥50 y (10.0)
Education	7 y	≤6 y (45.8) 7-11 y (34.1) 12 y (13.0) >12 y (7.1)
Annual gross family income	\$12 000	<\$10 000 (38.5) \$10 000-24 999 (52.4) ≥\$30 000 (9.1)
Household size	5 persons	
Marital status	NA	Single (10.6) Married (74.3) Other (15.1)
Employment status	NA	Full time (3.7) Part time (14.5) Student (2.7) Homemaker (73.4) Other (5.7)
Country of origin	NA	United States (4.7) Mexico (92.4) Other Spanish-speaking countries (2.9)
Years in the United States	8 y	≤5 y (36.3) >5 y (63.7)
Language of interview	NA	English (3.1) Spanish (96.9)
Language spoken and read in general	NA	English only (0.8) English better (2.0) English/Spanish (6.4) Spanish better (11.7) Spanish only (79.1)
Acculturation (scale from 1 to 5)	2	NA
Health insurance	NA	None (62.4) Private (16.2) Medical (20.4) Medicare (1.0)
Regular health care provider for general care	NA	Yes (57.8) No (42.2)
Regular health care provider for female care	NA	Yes (55.9) No (44.1)

\*NA = not applicable.

importance of Spanish language materials and bilingual, bicultural project staff. Regarding access to health care services, more than 60% of the women had no health insurance, and more than 40% did not have a regular health care provider.

## Experimental Design

The impact evaluation relies on a randomized experimental-control group design with pretest, post-test, and follow-up. The unit of randomization was the *consejera*. Pretest and post-test measures were collected before and after the 12 educational sessions. In addition, two follow-ups are scheduled 1 year and 2 years after the pretest, respectively.

A total of 36 *consejeras* conducted the group educational sessions. Each *consejera* conducted only one group. Half of the *consejeras* were randomly assigned to a control group, in which they participated in an equally engaging program entitled "Community Living Skills." The experimental group attended sessions on recognizing and preventing cancer, the importance of screening tests, nutri-

tion, skills training in breast self-examination, and obtaining services (see Table 1). Table 3 summarizes the activities in the control group.

## Measures

The effects of the *Por La Vida* intervention are investigated through extensive face-to-face interviews conducted with project participants. A 178-item survey was developed that covers information on access to health care services, cancer knowledge, preventive measures, and previous cancer-screening examinations. The primary source for the interview questions was an early draft of the Community Survey of Noncommunicable Disease Prevention (Project Salud, Texas Department of Health). Two additional scales were included: 1) the Short Acculturation Scale for Hispanics (35) and 2) the Social Support Scale (36). The English version of the questionnaire was translated to Spanish and four bilingual *Por La Vida* staff members independently reviewed the translation for accuracy and language adequacy in the target population. Discrepancies among the reviewers were resolved in a joint meeting, and pertinent changes were made.

Currently, pretest and post-test measurements have been completed, and follow-up interviews are under way. To complement self-report measures, the research protocol includes contacting health care providers of *Por La Vida* participants who report having had a mammogram and/or a Pap test in the past 2 years. We intend to study the validity of self-reports by obtaining information from medical records regarding the last mammogram and/or Pap test completed.

Furthermore, we examined the extent to which the intervention was implemented as planned in the experimental and control groups. The treatment implementation was investigated through quantitative and qualitative methods, including the following procedures:

1) Collection of detailed attendance records: Attendance records were collected at each educational session through sign-up sheets for regular program participants as well as invitees present at the session. Baby sitter's name and number of children present, if any, were also recorded.

2) Unobtrusive observations of ongoing sessions: Standardized forms were completed after the observation was conducted by the *Por La Vida* staff. Ratings referred to the extent to which the educational objectives for the session had been accomplished and the extent to which the *consejera* had followed the *Por La Vida* manual and provided an appropriate role model for the group participants.

3) Debriefing sessions with *consejeras*: Monthly meetings were held with *consejeras* during the time period in which the educational sessions were being conducted. The meetings provided an opportunity to identify potential problems and highlights of the intervention in progress, to clarify questions regarding the project, and to allow the *consejeras* to learn from each other's experiences.

**Table 3.** Topics of the *Por La Vida* educational sessions for community living skills (control group)\*

Weekly session No.	Topic of weekly sessions
1	Introduction
2	The Fountain of My Life
3	Amnesty, Immigration, and Citizenship
4	Job Training and Vocational Education
5	Home Budgeting
6	Social Security Information
7	Drug Identification and Information
8	Low-Cost Recreational Activities
9	Personal Self-defense
10	Saving Money on Utilities
11	Home Disaster Preparedness
12	Happy Child I
13	Happy Child II
14	Graduation
	Topic of additional sessions
	Crafts
	Assertiveness Training

\*The intervention comprised a total of 12 weekly sessions. Each group chose nine of the 11 topics listed as 3 through 13.

4) Interviews with consejeras: Extensive face-to-face interviews were conducted with each of the consejeras after completion of the group sessions. The interviews were semistructured, and the topics included evaluations about the training received, methods used for recruitment of participants, information about implementation of the intervention (i.e., location, average duration of sessions, use of provided materials, and preparation for sessions), and effects of the *Por La Vida* program on project participants as perceived by the respective consejera.

## Results

### Base-line Data

Table 4 summarizes the percentage of participants experiencing difficulties obtaining health care services within the past year and offers reasons why. The most common reason for not obtaining care was that the services were too expensive. Thirty-four percent of the sample found it difficult to obtain services because of the cost. Other common reasons included long waiting times to obtain appointments and to see practitioners once in the clinic, not knowing where to go for the services, inconvenient hours, lack of transportation, and interference with work. In addition, cultural barriers were also apparent for about 10% of the respondents. These barriers included not having Spanish-speaking office staffs, clinics not having Latina staff, and disrespectful behavior by office staff. Furthermore, nearly 10% of the women did not have confidence in the providers.

Knowledge and attitudes regarding breast cancer screening are summarized in Table 5. Nearly three quarters of the women reported that they knew how to do breast self-examinations, but fewer than half of the women could correctly report the recommended frequency of one per month. Two thirds of the women had heard of a mammogram. Over half of the women older than 40 years reported that they should have a mammogram every year. Sixty-four percent reported that they intended to have a mammogram in the next year.

Even among these low-income women, more than 60% reported that they would pay \$50 to obtain a mammogram. Although expense was the most commonly listed reason for not obtaining a mammogram, it was reported by only about 15% of the respondents. Most women worried about getting breast cancer, but most had positive outcome expectations. Fifty-eight per-

cent indicated that the chances of surviving breast cancer were good if the cancer was detected early.

Rates of self-reported breast and cervical cancer-screening tests for different age groups are presented in Table 6. For women under 50 years of age, approximately 30% performed breast self-examination monthly. A smaller proportion of women 50 years old or older performed these examinations on a monthly basis. In all age categories, approximately 20% had never had a professional physical breast examination. Having had a mammogram in the last year was related to age. Only 4.5% of women less than 40 years of age had received a mammogram in the past year. This rate increased to 22% for the women in the age group 40-49 years and to 35% for women 50 years old or older. Nevertheless, 47.1% of women 50 years old or older had never received a mammogram. Having had a Pap smear within the last year was not related to age. Approximately

**Table 5.** Knowledge and attitudes regarding breast cancer-screening examinations among *Por La Vida* participants (n = 512)

Variable	%
Knows how to do breast self-examination (BSE)	73.4
Knows recommended BSE frequency	45.2
Knows best time to perform BSE	21.8
Ever heard of a mammogram	66.8
Recommended frequency of mammogram for her age group*	
Yearly	54.9
2-3 y	8.2
Other	36.9
BSE named as early-detection examination	1.0
Physical breast examination named as early-detection examination	8.0
Mammogram named as early-detection examination	17.0
Intends to have a mammogram next year*	64.2
Would pay \$50 for a mammogram*	61.7
Most frequent reasons for not having a mammogram recently:*	
Expensive	14.7
Not necessary	12.7
Doctor did not recommend	12.6
Negligence	11.6
No symptoms	7.4
Chances of surviving breast cancer are good if detected early	57.6
Worries a lot about breast cancer	67.1

\*Percentage for women 40 years old or older.

**Table 4.** Percentage of *Por La Vida* participants experiencing difficulties within the past year to obtain health care services (n = 512)

Difficulty	Encountered difficulty, %	Did not receive care because of difficulty, %
Costs were too high	34.0	37.6
Had to wait too long for an appointment	27.7	23.1
Did not know where to go	23.0	28.3
Had to wait too long in clinic	22.9	21.0
Hours were not convenient	19.5	21.5
Needed someone to take care of children	17.7	18.1
Care not available when needed	15.8	36.7
Lack of transportation	15.3	27.5
Had to lose pay from work	13.7	23.4
No one spoke Spanish at the office	10.9	11.0
No Latino staff at the clinic	10.1	15.8
Had no confidence in staff	9.7	14.4
Staff at the clinic was disrespectful	6.4	15.6

**Table 6.** Self-reported breast and cervical cancer-screening examinations among *Por La Vida* participants, by age group (n = 512)

Screening test	Recency of test	Age group, y		
		<40	40-49	≥50
Breast self-examination	Monthly	29.7	29.9	19.6
Physical breast examination	Within past year	56.3	39.0	48.0
	1-2 y	10.6	18.1	10.0
	>2 y	12.9	19.0	24.0
Mammogram	Never	20.3	23.8	18.0
	Within past year	4.5	22.4	35.3
	1-2 y	2.0	15.0	9.8
Pap smear	>2 y	1.6	3.7	7.9
	Never	91.8	58.9	47.1
	Within past year	51.0	43.0	49.0
	1-3 y	21.7	23.4	23.5
	>3 y	6.0	19.6	7.8
	Never	21.4	14.0	19.6



half of the women had had a Pap smear recently. However, about 20% of the women younger than age 40 as well as the women 50 years old or older had never had a Pap smear.

Table 7 shows some of the reasons for not having a Pap smear. Almost all of the women had heard of the Pap test (94.1%). However, misinformation about the test was common. For example, 12.4% of the women thought that Pap smears were necessary only during reproductive years. Nearly 17% of the women felt that Pap smears were unnecessary if previous tests gave normal results, and 11.4% reported that Pap smears were unnecessary after menopause. In addition, 17.2% reported that Pap smears were necessary only for women who had multiple sex partners.

In summary, predictors of ever having had a mammogram included having a regular health care provider, having insurance that would pay for the test, and knowing how frequently mammograms should be offered. Predictors of having had a Pap smear test included having a regular health care provider, knowledge of the recommended frequency for Pap smear tests, and having encountered fewer predisposing barriers to access regular health care.

## Treatment Implementation

Attendance records and observations of ongoing sessions provided information about the extent to which the intervention was implemented as intended. Based on attendance records, *Por La Vida* participants attended on average eight of the 12 educational sessions. In addition, one of six sessions conducted by any of the 36 consejeras was observed by *Por La Vida* staff. Based on the observation forms completed by *Por La Vida* staff,

**Table 7.** Knowledge and attitudes regarding cervical cancer-screening examinations among *Por La Vida* participants (n = 512)

Variable	%
Ever heard of a Pap test	94.1
Recommended frequency of Pap test for her age group	
Yearly	66.6
2-3 y	6.7
Other	26.7
Names Pap test as early-detection examination	43.0
Pap test needed only during years when having babies	12.4
After a couple of normal Pap tests, it is not necessary to have any more Pap tests	16.8
Women can tell if they have cervical cancer without any medical examinations	4.6
Latina women are more likely than other women to get cervical cancer	34.7
Women do not need Pap tests after menopause	11.4
My doctor should tell me when I need a Pap test	50.8
Women with hysterectomy do not need a Pap test	16.6
Women with tubal ligation do not need a Pap test	17.5
Only women who had many sex partners need Pap tests	17.2
Pap tests are painful	25.5
Pap tests are too expensive	17.9
Intends to have a Pap test next year	85.7
Most frequent reasons for not having a Pap smear recently	
Negligence	18.8
Expensive	15.8
Not necessary	7.9
No symptoms	6.7
Fear	5.5
Chances of surviving cervical cancer are good if detected early	57.4
Worries a lot about cervical cancer	74.3

average ratings suggested that attainment of objectives for the pertinent session was satisfactory (on a scale from 1 to 5: mean = 4.1; median = 4.3). With regard to overall rating of the extent to which the consejeras followed pertinent materials and provided an appropriate role model for participants, the mean was 4.3 (median = 4.4) on a scale from 1 (strongly disagree) to 5 (strongly agree).

Extensive interviews with consejeras also provided feedback regarding the implementation and outcomes of the intervention. These interviews indicated that all consejeras found materials provided and training very useful and helpful. Consejeras perceived that the interventions enhanced knowledge among program participants. In addition, they reported that the program promoted personal growth, self-esteem, and perceived well-being. The majority of the consejeras reported women in their group who had become active in social and community activities, mostly related to schools, after joining the *Por La Vida* group. The group sessions were perceived by program participants as an opportunity to learn and as a valuable source of social support.

## Preliminary *Por La Vida* Intervention Effects

Preliminary results reveal statistically significant changes in cancer prevention behavior in the experimental group but not in the control group. In the cancer prevention groups, the percentage of women 40 years old or older who ever had a mammogram increased from 51.8% at pretest to 64.3% at post-test ( $P = .04$ ), while there was no statistically significant increase in the control group (39.3% to 48.2%;  $P = .14$ ). In addition, the percentage of women 18 years old or older who ever had a Pap test increased from 83.0% at pretest to 86.2% at post-test ( $P = .26$ ) in the control group and from 80.4% to 93.5% in the cancer prevention intervention group ( $P < .001$ ) (Table 8). Differences between groups before the intervention were not statistically significant. After the 12 educational sessions, differences between intervention groups were statistically significant ( $P = .02$ ) for the Pap test but not for mammography ( $P = .08$ ).

## Discussion

The need for better health promotion programs in the Latino community is substantiated by the combination of a growing population, low socioeconomic and educational levels, high prevalence rates of particular disease, the lack of health insurance, and limited access to and low utilization of health ser-

**Table 8.** Self-reported lifetime breast and cervical cancer-screening examinations among *Por La Vida* participants before and after the weekly educational sessions, by intervention group

Screening test	Pretest, %		Post-test, %	
	Cancer prevention	Community living skills	Cancer prevention	Community living skills
Mammography* (n = 112)	51.8	39.3	64.3	48.2
Pap test (n = 358)	80.4	83.0	93.5	86.2

\*Percentage for women 40 years old or older.



vices. The *Por La Vida* model has proved to be effective in attracting low-income Latinas with low level of formal education to the health promotion program. It offers a clearly implementable, demonstrably effective, and culturally appropriate health promotion model for Latinas and potentially through them to their families as well.

### Theoretical Implications

Early evidence from the *Por La Vida* evaluation supports the application of the social learning theory. The theory suggests that performance of novel behaviors is contingent on the expectation that actions will lead to reward or punishment. Data from the base-line study indicate that high percentages of Latinas worry about breast cancer and cervical cancer. However, they may not expect significant benefits from early detection and treatment. For example, more than 40% of the women thought that the chances of surviving breast or cervical cancer would be poor if disease was detected early. Thus, one important obstacle to obtaining screening tests to be overcome is to improve the expectation of benefit of screening. In addition to outcome expectation, there may be serious limitations in efficacy expectations. These expectations are relevant to barriers between the expected benefit and the likelihood the behavior will be executed. Evidence from the base-line study suggests that expectations for obtaining tests may be hindered by high costs, long waiting times, and significant inconveniences. Thus, a program must both improve knowledge and provide specific skills necessary to overcome barriers.

The *Por La Vida* model takes advantage of existing peer relationships. The use of the *consejera* model is consistent with the social learning theory. Several studies have demonstrated the importance of social support in the maintenance of behavior change (37), and previous demonstrations have shown that social support can play an important role in improving health behavior (36). These results are generally consistent with previous applied (38) and theoretical (37) research on social support.

Evidence from the base-line study also indicates suboptimal rates of cancer-screening tests by Latinas. These findings are consistent with a substantial number of studies (1-3,12,39-41). Preliminary evidence suggests that the *Por La Vida* intervention may lead to significant increases in the rates of cancer-screening test use and Pap smear use.

### Community Implications

It is widely recognized that improving health promotion of special populations requires community-based interventions in the target community (1,42). It is also well documented that, when changes are promoted mainly by outsiders, community efforts are likely to decline after the projects cease; i.e., influences rooted in indigenous sources generally have greater sustaining power than those applied by outsiders for a limited time. Moreover, a major benefit of community-mediated programs is that they can mobilize the power of established community networks of influence for transmitting knowledge and cultivating beneficial patterns of behavior (14).

The *Por La Vida* model capitalizes on existing social networks in the Latino community. It provides information about cancer prevention to Latinas who traditionally constitute the

health "gatekeepers" of the family. Both enabling and predisposing factors constitute barriers to proper cancer screening among Latinas. Universal access to health care would remove some of the major financial barriers to cancer screening. The *Por La Vida* program attempts to overcome the substantial barriers by reaching out to low-income Latinas and by providing information regarding the availability of low-cost cancer-screening tests in the community. Program participants also learn about the acceptability and preventive nature of cancer-screening tests. Furthermore, the *Por La Vida* groups deal with women's anxiety and fears regarding cancer and provide social support for health-seeking behaviors. This support includes encouraging women not only to receive cancer-screening tests but also to pursue follow-up care, if indicated, based on the results of the cancer-screening tests. Upon request, *Por La Vida* project staff also assists *consejeras* to identify proper sources of medical care for women needing medical follow-up.

We plan to continue training Latino community lay workers to conduct cancer prevention educational sessions and to further develop educational materials to guide the group sessions. Furthermore, we plan to disseminate the knowledge acquired by project participants in the educational sessions to friends and family members and to evaluate the dissemination. Theoretical considerations and the feedback provided by *consejeras* and participants of previous *Por La Vida* projects suggest that the knowledge and skills acquired by *consejeras* and participants in the project will persist in the community after the project has been completed.

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# Use of Cancer-Screening Tests in the San Francisco Bay Area: Comparison of Latinos and Anglos

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**Background:** Compared with Anglos (non-Latino whites), incidences of breast and colorectal cancers are lower for Latinos and incidences of cervical cancer are higher for Latinos. In regional and national studies, Latinos obtain fewer cancer screening tests for cervical, breast, and colorectal cancers when compared with Anglo populations. It remains unclear if these differences are due solely to socioeconomic status. **Purpose:** To evaluate self-reported use of these tests by ethnicity, we conducted telephone interviews about the use of the Pap smear, clinical breast examination, mammogram, rectal examination, fecal occult blood test, and sigmoidoscopy. **Methods:** Cross-sectional, random-digit dialing telephone surveys of Latino and Anglo adults, 35-74 years of age, living in San Francisco and Alameda Counties, Calif. were used. A total of 798 Latinos (398 men and 408 women) and 436 Anglos (214 men and 222 women) completed the interview. **Results:** Age-adjusted rates showed that 82.0% of Latinas reported a Pap smear within 3 years compared with 85.1% of Anglo women. A clinical breast examination within 2 years was reported by 82.1% of Latinas and by 88.9% of Anglo women. Screening mammograms within 2 years were reported by 57.8% of Latinas and by 72.3% of Anglo women (difference = -14.5%; 95% confidence interval [CI] = -21.5, -7.5). Compared with Anglos, fewer Latinos reported digital-rectal examinations within 2 years (44.6% versus 61.8%; difference = -17.2%; 95% CI = -22.6, -11.8). There were no significant differences by ethnicity in obtaining a fecal occult blood test within 2 years (32.3% versus 34.0%) and sigmoidoscopy within 5 years (18.9% versus 21.5%). After adjusting for age, education, health insurance, employment, marital status, county of residence, and self-perceived health status, Latino ethnicity was a significant predictor only for digital-rectal examination within 2 years (odds ratio [OR] = 0.65; 95% CI = 0.49-0.86) and digital-rectal examination ever (OR = 0.54; 95% CI = 0.40-0.74). Latinos were significantly more likely to cite forgetfulness, lack of transportation, long wait for appointments, and need for child care as reasons for not having cancer screening tests. **Conclusion:** We conclude that after accounting for socioeconomic factors, Latino ethnicity is a relatively minor predictor of use of cancer screening tests. Increasing the availability of culturally appropriate educational materials and providing universal health care coverage are more important priorities to promote appropriate use of cancer screening tests by Latinos. [Monogr Natl Cancer Inst 18:147-153, 1995]

Early detection of selected cancers diagnosed by recommended screening tests of at-risk populations is likely to play an increasingly important role in cancer prevention strategies. Although guidelines published by national organizations differ somewhat, there is consensus on selected recommended tests, such as Pap smears and mammograms for women and sigmoidoscopy and fecal occult blood test for both men and women (1-3). Studies that evaluate population estimates of use of screening tests by ethnicity are essential in planning, implementing, and evaluating programs to promote the use of cancer screening tests by underserved populations. In addition, effective screening tests need to be made available to the target population to expect an impact on morbidity and mortality.

Available national and regional data indicate that compared with African Americans and Anglos (non-Latino whites), Latinos of all national backgrounds have lower rates of cancer at all sites, specifically breast, colorectal, and prostate cancers (4-11). However, invasive cervical cancer, especially among Mexican American women, occurs at a substantially higher rate among Latinas (4,7,11). The fact that uniform and appropriate ethnic identifiers have only recently been implemented will lead to more accurate assessment of rates over time. These observed differences by ethnicity may provide some clues to cancer epidemiologists investigating etiologic contributors to cancer, such as dietary habits, infectious agents, or undefined lifestyle factors. Regardless of these lower rates, breast, colorectal, prostate, and lung cancers continue to be the most frequent among Latino populations, and primary or secondary prevention measures need to be emphasized.

Over the past decade, lifetime and interval use of screening tests for breast and cervical cancers have increased substantially among all women in the United States. However, compared with Anglo women, self-reported rates of Pap smear use in the previous 3 years and of mammogram use in the previous 1-2 years continue to be lower for Latinas and African American women (12-14). Studies from Texas and California indicate that the gap between Latina and Anglo women varies by region, but fewer data are available for other areas (15-20). Much less infor-

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See "Notes" section following "References."



mation is available about ethnic differences in the use of colorectal cancer screening tests, and the available data indicate that lifetime and interval rates are much lower than for breast cancer screening tests for all populations (15,21). Efforts to identify facilitating factors as well as attitudinal and structural barriers are ongoing; these will be helpful in designing culturally appropriate cancer prevention programs in the future.

We conducted a population-based survey of Latino and Anglo adults in the San Francisco Bay Area to evaluate the use of cancer screening tests by ethnicity. This survey addressed similar questions as did an earlier study of members in a prepaid health plan (15); we are now able to compare cancer-screening rates by ethnicity after adjusting for health insurance coverage.

## Methods

### Sample Selection

Latino and Anglo adults (between ages 35 and 74 years and living in census tracts within San Francisco and Alameda Counties with at least 10% Latinos in the 1980 U.S. census) were eligible for the study (22). A household was considered to be eligible if the person answering the telephone self-identified as Latino or white or identified the majority of residents in the household as belonging to either group. Within a given household, the adult between 35 and 74 years of age who had most recently celebrated a birthday was invited to respond to the survey. Sample selection was defined by requiring a similar number of interviewed participants within each ethnic group by sex and county of residence to avoid women responding in disproportionate numbers. We sought to interview twice as many Latinos as Anglos to evaluate the effect of acculturation.

We used a modified two-stage Waksberg (23) random-digit dialing telephone method to sample participants in 49 census tracts in San Francisco County and in 134 census tracts in Alameda County. Six city streets were randomly selected to locate telephone prefixes. This procedure identified 92 three-digit prefixes in San Francisco and 135 three-digit prefixes in Alameda. Four digit-suffixes were randomly generated by computer, and these were added to the prefixes to generate seven-digit telephone numbers in San Francisco ( $n = 1782$ ) and in Alameda ( $n = 1514$ ). When a Latino household was identified, the first five digits comprised a Primary Sampling Unit (PSU). As part of this first-stage sampling procedure, we identified 265 five-digit PSUs (159 in San Francisco and 106 in Alameda) of 2411 working numbers. In the second stage, 99 randomly generated, two-digit suffixes were added to the 265 five-digit PSU prefixes.

### Questionnaire

The questionnaire administered was similar to that used in a previous study of members of a prepaid health plan (15,24). Focus groups were conducted to assess beliefs and attitudes about cancer, to assess awareness of recommended cancer screening tests, and to identify reasons for not obtaining these tests. Questionnaire items were developed in Spanish and translated into English with the use of standard double-translation techniques (25) and were pretested in both languages.

Items on the cancer screening tests first asked if the respondent had ever heard of the test; the interviewer then carefully described the test and asked if the respondent had ever had the test and had the test within a defined interval of time. Tests assessed included Pap smear, clinical breast examination, breast self-examination, and mammogram for women only. Both men and women were asked about digital-rectal examination, fecal occult blood test, and sigmoidoscopy. The defined time interval corresponded to the National Cancer Institute's screening recommendations and was modified as described below to allow for inaccurate respondent recall (2). The actual number of years since the last examination was recorded. Additional items included the reasons why a test was not done according to the recommended schedule, the respondent's perceptions of vulnerability to cancer and chances of curing cancer if detected early, and the respondent's preference for a male or female physician to conduct a pelvic and/or rectal examination.

Standard demographic items, including an acculturation scale (26), self-perceived health status, and health insurance coverage, were also asked. Acculturation scores ranged from 1 (least acculturated) to 5 (most acculturated) and were dichotomized into less acculturated (1 to <3) and more acculturated ( $\geq 3$  to 5). The questionnaire was administered, after verbal consent by telephone, by trained bilingual interviewers in approximately 20 minutes, between November 1990 and April 1991.

### Data Analysis

Data were analyzed with the use of standard techniques (27). Responses regarding cancer screening tests were classified according to whether the respondent had at least one lifetime examination and whether the procedure was performed in a defined interval of time. Time intervals for each test were defined as within 3 years for a Pap smear, within 1 month for a breast self-examination, within 2 years for a clinical breast examination, within 2 years for a mammogram, within 2 years for a digital-rectal examination, within 2 years for a fecal occult blood test, and within 5 years for a sigmoidoscopy (2). Calculations included the proportion of "yes" responses, the difference of "yes" responses between Latinos and Anglos, and the 95% confidence intervals (CIs) for the difference (28). We provided the CIs as a basis for evaluating the magnitude of the differences between Latinos and Anglos, even if these were not statistically significant (29). Rates for cancer screening tests were age adjusted to the 1990 San Francisco and Alameda Counties population by the direct method (30).

The effect of ethnicity on questionnaire responses was analyzed with the use of multivariate logistic regression models (27). Predictor variables included ethnicity (Anglo = 0; Latino = 1), years of formal education (in years as continuous variable), sex (women = 0; men = 1), age (in years as continuous variable), employment (yes = 0; no = 1), having health insurance (any insurance = 0; no insurance = 1), marital status (married = 0; not married = 1), self-perceived health status (excellent, good = 0; fair, poor = 1), and county of residence (Alameda = 0; San Francisco = 1). For multivariate analysis of the Latino sample only, acculturation (continuous) and birthplace (United States = 0; other = 1) were also included as predictor variables.

## Results

Of the 14 346 telephone calls that were made, 1242 (8.7%) completed interviews, 777 (5.4%) refused, 692 (4.8%) were not contacted, 8011 (55.8%) were ineligible by age or ethnicity criteria, and 3624 (25.3%) were nonworking numbers. The response rate of eligible persons was 62% (1242/2019; interviewed/interviewed plus refusals).

Compared with Anglos, Latinos averaged significantly fewer years of formal education (14.8 versus 10.1 years;  $P < .001$ ), but the proportion of women, average age, and percent employed were similar by ethnicity (Table 1). Compared with Anglos, there were significantly more Latinos with no more than a high school education (difference = 47.9%; 95% CI = 42.8-53.1), married (difference = 12.2%; 95% CI = 6.5-18.0), with an annual household income of less than \$30 000 (difference = 28.4%; 95% CI = 22.3-34.5), with no health insurance (difference = 12.9%; 95% CI = 8.7-17.2), and with fair or poor self-perceived health (difference = 18.1; 95% CI = 13.3-22.8).

Among the Latinos interviewed, 69% were born in Latin America, 66% were less acculturated, and the foreign born had lived an average of 27.3 years in the United States. Including U.S.-born Latinos, the majority were of Mexican (51.4%) or Central American (31.3%) background, with the remainder having family background from the rest of Latin America.

### Use of Cancer-Screening Tests by Women

Overall, 96.0% of Latinas and 96.3% of Anglo women reported having had at least one Pap smear. Latinas and Anglo



**Table 1.** Demographics of interviewed sample—adults living in San Francisco and Alameda Counties, 1991

Characteristic	Latinos		Anglos	
	No.	%	No.	%
Sex				
Men	398	49.4	214	49.1
Women	408	50.6	222	50.9
Education				
High school or less	596	74.3	115	26.4
Some college or more	206	25.7	321	73.6
Age, y				
35-49	487	60.7	268	61.5
50-74	315	39.3	168	38.5
Employment				
Full or part-time	534	66.5	279	64.0
Unemployed/retired	269	33.5	157	36.0
Marital status				
Married or living with	510	63.5	223	51.3
Single, divorced, or widowed	293	36.5	212	48.7
Income				
≥\$30 000	234	36.3	246	64.7
0 to <\$30 000	410	63.7	134	35.3
Health self-perception				
Excellent, good	532	66.3	368	84.4
Fair, poor	270	33.7	68	15.6
Health insurance				
Any insurance	605	75.3	383	88.2
No insurance	198	24.7	51	11.8

women reported similar rates of having had a Pap smear within the previous 3 years, although the difference approached statistical significance (Table 2). Of women who had had at least one Pap smear, 89% of Latinas and 93% of Anglo women reported that it was done as part of a routine examination.

A high proportion of Latinas (93.0%) and Anglo women (98.2%) reported having had at least one clinical breast examination. Compared with Anglo women, significantly fewer Latinas reported having had a clinical breast examination within the previous 2 years (Table 2). Most women (90% of Latinas and 94% of Anglo women) reported that the last clinical breast examination was part of a regular examination.

Compared with Anglo women, significantly fewer Latinas had heard of a mammogram (84.3% versus 99.5%;  $\chi^2 = 36$ ;  $P < .001$ ) or had had a mammogram in the previous 2 years, and a slightly higher proportion had never had a mammogram (Table 2). Among women who reported at least one mammogram and were at least 40 years of age, Latinas were somewhat less likely than Anglo women to have had a screening mammogram (85.0% versus 92.5%;  $\chi^2 = 4.3$ ;  $P < .04$ ) as opposed to a mammogram because of a problem.

Almost all Latinas (95.8%) and all Anglo women had heard of breast self-examination, but fewer Latinas reported knowing how to examine their breasts (86.5% versus 98.2%;  $\chi^2 = 23$ ;  $P < .001$ ). Latinas were just as likely to perform monthly breast self-examinations as Anglo women (57.1% versus 59.0%), and similar proportions reported that they had never performed breast self-examinations (16.9% versus 11.3%).

**Table 2.** Age-adjusted,\* self-reported rates of use of cancer-screening tests by Latinas and Anglo women living in San Francisco and Alameda Counties, 1991

	Latinas (n = 412) %	Anglo women (n = 302) %	Difference	95% CI of difference	
Pap test					
Had in past 3 y	82.0	85.1	-3.1	-8.6,	2.4
Had >3 y ago	14.0	11.2	2.8	-2.1,	7.7
Never had	4.0	3.7	0.3	-2.6,	3.2
Clinical breast examination					
Had in past 2 y	82.1	88.9	-6.8	-11.9,	-1.7
Had >2 y ago	10.9	9.3	1.6	-2.9,	6.1
Never had	7.0	1.8	5.2	2.3,	8.1
Mammogram†					
Had in past 2 y	57.8	72.3	-14.5	-21.5,	-7.5
Had >2 y ago	14.3	5.3	9.0	4.8,	13.2
Never had	27.9	22.4	5.5	-0.9,	11.9

\*Rates age adjusted by the direct method to the 1990 San Francisco and Alameda Counties population.

†For reported use of mammography, only respondents 40-74 years of age were included in the analysis.

### Men's Awareness of Recommended Cancer-Screening Tests for Women

Anglo men were more likely than Latinas to have heard of Pap smears (97.2% versus 64.6%;  $\chi^2 = 81$ ;  $P < .001$ ), clinical breast examination (97.7% versus 90.3%;  $\chi^2 = 11$ ;  $P = .001$ ), and mammography (95.3% versus 76.0%;  $\chi^2 = 36$ ;  $P < .001$ ).

### Use of Colorectal Cancer-Screening Tests

Compared with Anglos, Latinas of both sexes were significantly less likely to have heard of digital-rectal examination (81.9% versus 97.2%;  $\chi^2 = 59$ ;  $P < .001$ ), fecal occult blood test (47.0% versus 62.3%;  $\chi^2 = 26$ ;  $P < .001$ ), or sigmoidoscopy (15.0% versus 42.8%;  $\chi^2 = 117$ ;  $P < .001$ ). Among respondents 40-74 years of age, Latinas were significantly less likely to have had a digital-rectal examination within the previous 2 years or at least one digital-rectal examination ever (Table 3). Analysis of the use of fecal occult blood test or sigmoidoscopy showed no significant differences between Latinas and Anglos for use within the defined time interval or at least once (Table 3). Of Latino and Anglo respondents, respectively, who reported having had the screening test, "routine examination" was the reason given by most for having the digital-rectal examination (71% versus 77%), fecal occult blood test (64% versus 71%), and sigmoidoscopy (34% versus 23%).

### Multivariate Analysis

After adjusting for education, age, employment, marital status, health insurance coverage, self-perceived health, and county of residence, ethnicity was not a significant predictor for use of Pap smears in the previous 3 years, for clinical breast examination in the previous 2 years, for breast self-examination in the past month, or for mammograms at least once or in the previous 2 years (Table 4).

Older women were significantly more likely to have ever had a mammogram (odds ratio [OR] = 2.3; 95% CI = 1.9-2.7) or to

**Table 3.** Age-adjusted,\* self-reported rates of use of cancer-screening tests for colorectal cancer by Latinos and Anglos living in San Francisco and Alameda Counties, 1991

	Latinos (n = 844), %	Anglos (n = 510), %	Difference	95% CI of difference
Digital-rectal examination				
Had in past 2 y	44.6	61.8	-17.2	-22.6, -11.8
Had >2 y ago	18.1	19.0	-0.9	-5.2, 3.4
Never had	37.3	19.2	18.1	13.4, 22.8
Fecal occult blood test†				
Had in past 2 y	32.3	34.0	-1.7	-6.9, 3.5
Had >2 y ago	10.1	10.3	-0.2	-3.5, 3.1
Never had	56.6	55.7	0.9	-4.6, 6.4
Sigmoidoscopy‡				
Had in past 5 y	18.9	21.5	-2.6	-7.1, 1.9
Had >5 y ago	7.4	7.5	-0.1	-3.0, 2.8
Never had	73.6	71.0	2.6	-2.4, 7.6

\*Rates age adjusted by the direct method to the 1990 San Francisco and Alameda Counties population.

†For reported use of digital-rectal examination and fecal occult blood test, only respondents 40-74 years of age were included in the analysis.

‡For reported use of sigmoidoscopy, only respondents 50-74 years of age were included in the analysis.

**Table 4.** Adjusted\* OR for Latino ethnicity as a predictor of self-reported use of cancer screening tests in San Francisco and Alameda Counties, 1991

Cancer screening test	OR (95% CI)	P
Ever had mammogram	0.96 (0.61-1.50)	ns†
Mammogram within 2 y	0.77 (0.51-1.17)	ns
Pap smear within 3 y	0.77 (0.38-1.54)	ns
Clinical breast examination within 2 y	0.58 (0.32-1.08)	ns
Breast self-examination within 1 mo	0.95 (0.64-1.41)	ns
Ever had digital-rectal examination	0.54 (0.40-0.74)	<.001
Digital-rectal examination within 2 y	0.65 (0.49-0.86)	.002
Ever had fecal occult blood test	1.15 (0.84-1.57)	ns
Fecal occult blood test within 2 y	1.31 (0.93-1.85)	ns
Ever had a sigmoidoscopy	0.95 (0.66-1.37)	ns
Sigmoidoscopy within 5 y	0.95 (0.63-1.43)	ns

\*Adjusted for education ( $\geq 12$  y = 0;  $< 12$  y = 1), sex where appropriate (women = 0; men = 1), age (35-49 y = 0; 50-74 y = 1), employment (yes = 0; no = 1), marital status (married = 0; other = 1), county of residence (Alameda = 0; San Francisco = 1), and self-perceived health (good, excellent = 0; fair, poor = 1).

†ns = not significant.

have had a mammogram in the past 2 years (OR = 1.9; 95% CI = 1.6-2.3) and were significantly less likely to have had a Pap smear in the previous 3 years (OR = 0.6; 95% CI = 0.5-0.8). Women with more years of education were more likely to have had a Pap smear in the previous 3 years (OR = 1.8; 95% CI = 1.3-2.6). Women with health insurance were significantly more likely to have ever had a mammogram (OR = 2.2; 95% CI = 1.4-3.4) and to have had a mammogram in the previous 2 years (OR = 1.9; 95% CI = 1.2-3.0). Having employment and being married were also significant predictors of use of mammograms in the previous 2 years.

After adjusting for sex, education, age, employment, marital status, self-perceived health, and county of residence, Latinos were significantly less likely than Anglos to have had at least

one digital-rectal examination or a digital-rectal examination in the previous 2 years (Table 4). In the multivariate model, Latino ethnicity was not a significant predictor for having had a fecal occult blood test or sigmoidoscopy ever or within the defined time interval (Table 4).

Persons with health insurance were significantly more likely to have had a digital-rectal examination in the previous 2 years (OR = 2.2; 95% CI = 1.6-3.1), a fecal occult blood test in the previous 2 years (OR = 2.1; 95% CI = 1.4-3.2), and a sigmoidoscopy in the previous 5 years (OR = 1.8; 95% CI = 1.1-3.0). Older persons and those with more years of education were also significantly more likely to have had a digital-rectal examination in the previous 2 years (OR = 1.5; 95% CI = 1.3-1.5 for age; OR = 1.3; 95% CI = 1.1-1.5 for education), a fecal occult blood test in the previous 2 years (OR = 2.0; 95% CI = 1.7-2.3 for age; OR = 1.3; 95% CI = 1.1-1.5 for education), and a sigmoidoscopy in the previous 5 years (OR = 1.5; 95% CI = 1.2-1.7 for age; OR = 1.4; 95% CI = 1.1-1.7 for education).

To identify ethnic-specific predictors of use of cancer-screening tests, the multivariate analysis was conducted with the Latino sample only by adding acculturation and birthplace as predictor variables. Having had a clinical breast examination in the previous 2 years was the only test where being more acculturated (OR = 1.5; 95% CI = 1.0-2.3) and being born in the United States (OR = 3.3; 95% CI = 1.20-9.0) were significant predictors. Otherwise, acculturation and birthplace were not significant predictors of use of cancer-screening tests after accounting for other variables. Similar to the entire sample, age, education, employment, and marital status were significant predictors of use of cancer-screening tests among Latinos.

### Barriers to Obtaining Cancer Screening Tests

A greater proportion of Latinos compared with Anglos thought that they were not likely to develop cancer (Table 5). Among respondents with at least one Pap smear or mammogram during her lifetime, Latinas were less likely than Anglo women to estimate that the chances were "excellent or good" of being cured if cervical cancer was detected early (83.3% versus 93.0%;  $\chi^2 = 11$ ;  $P < .01$ ) and if breast cancer was detected early (83.0% versus 94.0%;  $\chi^2 = 14$ ;  $P = .001$ ). A similar proportion of Latinos and Anglos, respectively thought that prostate (85% versus 93%) and colorectal (75% versus 78%) cancers had an "excellent or good" chance of being cured if found early.

In exploring reasons why respondents may not have had recommended cancer-screening tests, Latinos were more likely than Anglos to report forgetfulness or carelessness, lack of transportation, long wait for examinations, and need for child care as reasons for not having tests (Table 5). A greater proportion of Anglos cited embarrassment of tests as a reason for not having examinations (Table 5).

Preference for a physician of the same sex to perform a pelvic and/or rectal examination was important for 45.7% of Latinos and 41.7% of Anglos overall. Latino and Anglo men, respectively, preferred a male physician in similar proportions (31% versus 34%), and Latinas and Anglo women, respectively, preferred a woman physician in similar proportions (44% versus 37%;  $\chi^2 = 3.3$ ;  $P = .19$ ). Finally, of the Latinos who responded to the questionnaire in Spanish, 56.5% (n = 269) of the men and



**Table 5.** Perception of vulnerability and barriers to having cancer screening examinations among Latino and Anglo adults in San Francisco and Alameda Counties, 1991

	Latinos (n = 806), %	Anglos (n = 436), %	Difference* %	95% CI of difference
How likely are you to get cancer?				
Not too likely/not likely at all	66.7	48.4	18.4	12.6, 24.1
Reasons given for not having tests:				
Felt well	83.9	85.1	-1.2	-5.4, 3.0
Forgetfulness/carelessness	83.1	75.0	8.1	3.3, 12.9
Fear of results	74.7	79.0	-4.3	-9.2, 0.5
Examinations are embarrassing	47.3	53.2	-5.9	-11.8, -0.1
Physician did not recommend	42.7	43.6	-0.9	-6.7, 4.9
Unaware of examination	61.9	64.0	-2.1	-7.7, 3.5
Expensive	67.5	71.3	-3.8	-9.2, 1.5
Lack of transportation	27.7	11.5	16.2	11.9, 20.5
Long wait	41.6	22.3	19.3	14.2, 24.5
Need for child care	11.1	6.4	4.6	1.5, 7.8

\*Difference of % Latinos minus % Anglos.

71.7% (n = 261) of the women preferred a physician who spoke or understood Spanish well.

## Discussion

Differences in use of diagnostic services by race and ethnicity have been found for cardiac procedures, although it remains unclear whether socioeconomic status, institutional barriers, or specific cultural factors account for these observations (31-33). National and regional studies have compared rates for use of Pap smears and mammograms by race and ethnicity, and in general find that compared with Anglo women, Latinas obtain fewer tests (12-14,16-20). In a previous study (15), we found that Latinos were less likely to obtain screening tests for colorectal cancer, although ethnic differences for use of mammography were explained by confounding variables. This study allowed us to compare a population-based sample of Latino and Anglo adults with significant differences in health insurance coverage.

Our results showed that compared with Anglos, Latinos were significantly less likely to report lifetime and interval clinical breast examination, mammogram, and digital-rectal examination. There were no differences by ethnicity in obtaining Pap smears, fecal occult blood tests, or sigmoidoscopy, either over lifetime or at the recommended intervals. However, after adjusting for demographic and socioeconomic variables, significant differences remained only for digital-rectal examination. The implications of these findings are that, despite observed differences in attitudes and beliefs about cancer and possible cultural factors that may keep Latinos from obtaining preventive services, much of the difference may be explained by access and socioeconomic factors.

We found that Pap smear use is high in the San Francisco Bay Area, and in this sample of women (35-74 years of age), compliance with recommended interval screening exceeded 80% in both ethnic groups. Compared with other published studies, San Francisco Bay Area Latinas and Anglo women report higher rates of interval Pap smears; nearly all have had at least one test

during their lifetime (Table 6) (14,17,34). As in our previous study (15), we found that older women and women with fewer years of education of either ethnic group were less likely to have had a Pap smear within 3 years; health insurance coverage did not predict Pap smear use. Thus, programs to increase appropriate use of Pap smears may need to focus on older women who are at increased risk of dying of cervical cancer and on women with no more than a high school education (35).

Screening mammograms with or without a clinical examination for breast cancer have been demonstrated in randomized control studies to decrease mortality from the disease by about 30% (36). Although controversies persist as to the age at which to begin screening and the interval between tests, a major public health effort has been made in the past 5 years to increase use of mammography by educating women and increasing access. In fact, analyses of the National Health Interview Survey indicate that by 1990, reported use of screening mammograms in the previous year had more than doubled (12). Review of published studies (12,13,16,19) that include reported rates for Latinas show a temporal trend to increased use, although regional variation may be more important in determining interval screening rates (Table 6). Furthermore, some variation in screening rates may be a result of different data collection methods.

Our study found that Latinas were significantly less likely than Anglo women to report having had a clinical breast examination or a screening mammogram in the previous 2 years. The absolute difference in age-adjusted rates was only 6.8% for clinical breast examination, but increased to 14.5% for mammograms. However, after adjusting for other confounding variables, these findings were no longer statistically significant. The

**Table 6.** Reported rates of lifetime and interval use of Pap smears and mammograms by Latinas in national and regional surveys

Study* (ref. No.)	Years	Pap smear (%)		Mammogram (%)	
		Ever	Interval	Ever	Interval
HHANES (34)	1982-1984	80	75†	—	—
Los Angeles (16)	1984-1985	—	—	26	20†
Texas (18)	1987	—	—	24	—
NHIS (13,14)	1987	76	65†	65	42† 13‡
NHIS (12)	1990	—	—	—	31†
San Diego (17)	1989	—	—	—	—
High accult		82	60‡	58	—
Low accult		73	44	27	—
San Francisco (20)	1989	76	—	74	—
Los Angeles (40)	1990	—	—	—	—
Spanish		—	—	14	—
English		—	—	47	—
El Paso, Tex. (19)	1990	—	46§	—	21§
KPMCP, N. Calif. (15)	1990	97	87†	75	65§
SF Bay Area (this study)	1991	96	82†	72	58§

\*HHANES = Hispanic Health and Nutrition Examination Survey; NHIS = National Health Interview Survey; KPMCP = Kaiser Permanente Medical Care Program.

†Interval time = 3 y.

‡Interval time = 1 y.

§Interval time = 2 y.



calculated ORs were 0.77 for mammogram in the previous 2 years and 0.58 for clinical breast examination in the previous 2 years, and these approached statistical significance. Studies with a larger sample size may be better able to disentangle the roles of ethnicity and socioeconomic factors in the use of these preventive services. Our analysis did show that being employed and having health insurance were significant predictors for obtaining screening mammograms. Furthermore, we also found that older and married women were more likely to obtain mammograms in the previous 2 years. Although cultural factors may play a role in Latinas obtaining mammograms, economic barriers seem to be of greater importance.

Contrasting the somewhat optimistic findings for the use of breast and cervical cancer-screening tests, rates for the use of colorectal cancer-screening tests were considerably lower in both Latinos and Anglos. Digital-rectal examination had the highest reported lifetime and interval rates in both ethnic groups, and Latinos were significantly less likely to obtain this test even after adjusting for confounding variables. However, there is little evidence to recommend digital-rectal examination for colorectal cancer screening, and although of potential use in screening for prostate cancer, there is much controversy (3).

Data to support routine use of screening fecal occult blood tests and sigmoidoscopy for early detection of colorectal cancer have been published since the time this survey was conducted (37,38). Clinician enthusiasm for recommending these tests may be increasing and will likely be reinforced by the recommendations of the U.S. Preventive Task Force (3). Our observations that only about one third of respondents had had a fecal occult blood test in the previous 2 years and that only about one quarter reported a sigmoidoscopy in their lifetime indicate that much public education is needed on this topic. Although we did not find significant differences by ethnicity for interval use of fecal occult blood tests or sigmoidoscopy in either univariate or multivariate analyses, having health insurance, being older, and having more education were significantly associated with obtaining colorectal cancer screening tests. To affect mortality from colorectal cancer in all ethnic groups, campaigns similar to those for breast and cervical cancers (39) to raise the level of awareness and facilitate access to effective screening tests need to be considered a national priority.

In an effort to evaluate Latino ethnic-specific factors that may account for differences in the use of cancer-screening tests, we found that being more acculturated and born in the United States were significant predictors only for obtaining clinical breast examination. This differs from earlier studies in San Diego (17) and Los Angeles (40) that found acculturation and language preference to be important determinants in the use of cancer screening tests among Latinas (Table 6), but is consistent with findings from our earlier study of members of a prepaid health plan (15). Additional research that compares Latinos from different regions of the country with the same questionnaire will be useful in determining whether these observations reflect regional differences or temporal trends.

Ethnic differences in barriers to obtaining cancer-screening tests were also observed. We again found that compared with Anglos, Latinos perceived less vulnerability to developing cancer. Both ethnic groups cited the same five reasons most fre-

quently for not having tests, and Latinos were more likely to claim forgetfulness or carelessness as a reason. However, lack of transportation, need for child care, and long waits for appointments were significantly more likely to be mentioned by Latino respondents than by Anglos. These structural barriers may be due in part to underlying socioeconomic and demographic differences but could be potentially addressed with changes in the health care system.

Preference for the same-sex clinician was not significantly different by ethnicity, although other data suggest that women physicians may be more effective at providing preventive services. Although most Latinos who responded to the questionnaire in Spanish preferred a physician who speaks Spanish, 36% claimed that this did not matter. Two studies (41,42) indicate that Spanish language concordance between physicians and patients resulted in better compliance with medications and appointments and in more questions asked and greater recall of recommendations than their counterparts seen by non-Spanish-speaking clinicians. Increasing the number of Spanish-speaking clinicians may be an additional component in facilitating access to preventive services by Latinos.

This study has several important limitations. The interview completion rate was 62% of all known eligible persons contacted. Persons completing the survey may be more likely to report compliance with recommended screening tests and as a result may somewhat inflate the rates obtained. The fact that our rates are similar to those reported by other studies in this area would indicate that this is not a significant factor. Furthermore, there is no reason to believe that there would be differential responses by ethnicity in reporting cancer-screening tests. An additional concern is that our data are based on self-reports, and these were not validated by medical record reviews. Overall, patients have been found to overestimate how recently a cancer-screening test was done when self-reports were compared with medical records (43,44). Finally, these results have limited generalizability because Latinos in the San Francisco Bay Area have higher than average socioeconomic status, are predominantly of Mexican and Central American background, and have low-cost cancer-screening programs available through the public health system. Similar studies with other Latino populations are needed.

At the time we embarked on this project, we had expected to find few differences in the survey of a prepaid health plan population and more striking differences in the population-based survey. Our findings in the two surveys were similar, and, in fact, fewer differences in cancer-screening test use were found in the current study after accounting for health insurance coverage and socioeconomic status. Although cultural factors clearly influence attitudes, these may have limited contribution in affecting behavior after accounting for socioeconomic status. The almost complete absence of acculturation as an important predictor of cancer-screening behavior also contrasts with observations about cigarette smoking and alcohol use among women (45,46).

On the basis of our data, we conclude that ethnicity is a relatively minor predictor of use of cancer-screening tests after accounting for socioeconomic factors. Increasing the availability of culturally appropriate educational materials and providing universal health care coverage are more important priorities to promote appropriate use of cancer-screening tests by Latinos.



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# Effectiveness of Disseminating Culturally Appropriate Smoking-Cessation Information: *Programa Latino Para Dejar de Fumar*

Gerardo Marín, Eliseo J. Pérez-Stable\*

**Background:** The need for a culturally appropriate smoking-cessation intervention for Latinos is based on data on current patterns of tobacco use, possible targeting by the tobacco industry, and the lack of smoking-cessation interventions that are appropriate to the cultural characteristics of Latino smokers. **Purpose:** Our goal was to evaluate the effectiveness of the *Programa Latino Para Dejar de Fumar* (PLDF) in disseminating smoking-cessation information in San Francisco's Latino community. **Methods:** Annual cross-sectional telephone surveys were conducted from 1986 to 1993 of Latino adults, 18-65 years of age, living in census tracts with at least 10% Latinos. Surveys in 1986 and 1987 formed the base line for comparison of PLDF effects. **Results:** Awareness of a Hispanic smoking-cessation program (odds ratio [OR] = 1.11; 95% confidence interval [CI] = 1.09-1.14), awareness of PLDF specifically (OR = 1.14; 95% CI = 1.10-1.17), awareness of available printed information to help smokers quit (OR = 1.09; 95% CI = 1.06-1.12), and having a copy of the *Guía Para Dejar de Fumar* (OR = 1.09; 95% CI = 1.05-1.14) were significantly associated with year of survey. In addition, those same variables were significantly associated with a lower acculturation score (respective ORs = 3.95, and 95% CI = 3.57-4.37; OR = 5.40, and 95% CI = 4.86-6.01; OR = 0.63, and 95% CI = 0.58-0.69; and OR = 4.54, and 95% CI = 3.89-5.30). Women were more likely than men to report awareness of a Hispanic smoking-cessation program (OR = 0.88; 95% CI = 0.81-0.96), awareness of PLDF (OR = 0.84; 95% CI = 0.77-0.92), and awareness of available printed information (OR = 0.78; 95% CI = 0.72-0.85). Cigarette-smoking prevalence decreased from 1986 through 1990, stabilized in 1991, and appeared to increase among all groups in 1993. Prevalence of smoking cessation remained stable overall, but it showed a steady increase among less acculturated respondents. **Conclusion:** We conclude that a culturally appropriate community intervention to promote nonsmoking can be successful at disseminating information about smoking cessation. Latino community norms about smoking are evolving, leading to decreased social acceptability. [Monogr Natl Cancer Inst 18:155-163, 1995]

Despite the increasing demographic importance of Latinos<sup>1</sup> (1), few attempts have been made at developing culturally appropriate smoking-cessation interventions for Hispanics (2-5).

The need for a culturally appropriate smoking-cessation intervention for Hispanics is based on data on current patterns of tobacco use among Hispanics in the United States, the possible targeting of Hispanics by the tobacco industry (6), and the dearth of smoking-cessation interventions that are appropriate to the cultural characteristics of Hispanic smokers (3).

This article summarizes the effectiveness of a culturally appropriate community intervention to increase awareness of how to change cigarette-smoking behavior among adult Hispanics in San Francisco, Calif. The intervention has been more fully described in a previous publication (7).

The program (known in Spanish as *Programa Latino Para Dejar de Fumar* or PLDF) began in 1985 with funding from the National Cancer Institute and targeted less acculturated Hispanics with a multicomponent community-wide intervention to promote smoking cessation (7). The ultimate objective of PLDF was to lower cigarette-smoking prevalence among the less acculturated Latino residents of San Francisco. As described below, the PLDF was designed after a thorough investigation of the values, norms, attitudes, and expectancies of Hispanic smokers (8-12), while incorporating such basic Hispanic cultural values as "familialism" (13,14) and "simpatía" (15) and employing culturally appropriate strategies and channels (16). The PLDF was designed as a multicomponent cessation intervention that would contribute to the existing gap in knowledge and develop and evaluate culturally appropriate materials for Hispanic smokers.

The first population-based survey prior to the beginning of the intervention showed that the less acculturated Hispanic men in San Francisco had a cigarette-smoking prevalence of 37.5% compared with only 13.6% of the less acculturated Hispanic women (17). Results from the 1992 National Health Interview Survey (NHIS) showed that rates of current smokers for men and women, respectively, vary by race and ethnicity, with 23.6% and 18.0% among Hispanics, 28.6% and 25.9% among non-Hispanic whites, 32.3% and 24.1% among African-

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See "Notes" section following "References."



Americans, and 26.3% and 4.0% among Asians and Pacific Islanders (18). The survey findings of lower cigarette smoking among Latinos are supported by the substantially lower mortality rates, compared with those among non-Hispanic whites and African-Americans, from all smoking-related cancers (except cervical cancer), ischemic heart disease, stroke, and chronic obstructive pulmonary disease (19).

In the first report on the intervention effects, we (20) documented a marked increase in awareness of PLDF activities among less acculturated Hispanics in San Francisco: from 24.9% and 29.2% at base-line surveys to 48.5% after only 7 months of community intervention. At that time, a number of the less acculturated Latino current smokers (12% of men and 23% of women) had a copy of the PLDF smoking-cessation manual (20). Subsequently, we (21) analyzed the effects of the intervention on smoking prevalence after a fourth cross-sectional survey and 19 months of community intervention. We defined "exposure" to the intervention by affirmative responses to questions about recognizing the PLDF name; having heard, seen, or read PLDF cessation information in various media; and having the PLDF smoking-cessation manual. This exposure index was used as the primary predictor variable. Although smoking prevalence decreased, quitting smoking in the 12 months prior to the survey was unrelated to exposure to PLDF. Among current smokers, high exposure to PLDF was associated with smoking fewer cigarettes per day (odds ratio [OR] = 2.0; 95% confidence interval [CI] = 1.2-3.2;  $P = .007$ ), more attempts to quit (OR = 1.6; 95% CI = 1.0-2.5;  $P = .06$ ), having been asked to quit (OR = 2.2; 95% CI = 1.4-3.5;  $P < .001$ ), knowledge of how to obtain smoking-cessation materials (OR = 2.5; 95% CI = 1.5-4.0;  $P < .001$ ), and awareness of a smoking-cessation raffle (OR = 12.2; 95% CI = 5.3-28.1;  $P < .001$ ) (21).

This article briefly describes the community intervention, its major components, and the community in which it was tested. Our main objective was to present updated results on the effects of the PLDF intervention on dissemination of cessation information after 6 years, using cross-sectional survey data from 1986 through 1991 and from 1993. In addition, we present unadjusted cigarette-smoking and cessation rates (or "quit ratio") for the community at large.

## Methods

### Community Intervention

The PLDF community intervention targeted two specific groups among the less acculturated Latinos in San Francisco, Calif.: 1) those currently smoking cigarettes and 2) nonsmokers who may know relatives or friends who smoke. A variety of media channels (television, radio, pamphlets, personalized consultations, and a self-help manual) were used to motivate smokers to quit smoking and to provide behavioral guidance to smokers on how to quit smoking and to nonsmokers on how to influence smokers to quit.

The specific content of these messages reflected the initial set of studies that identified the group-specific attitudes, values, norms, and expectancies of Hispanic smokers (8-12). A significant portion of this early research was based on the Theory of Reasoned Action (22). The analysis of the initial formative research showed that the bad smell of cigarettes, improving relationships with relatives, the desire not to provide a bad example to children, the ability to breathe more easily, and having a better taste in one's mouth were consequences of smoking and quitting that most strongly discriminated between those Hispanics intending to quit and those planning to continue smoking (10).

The informational and motivational messages were presented through a variety of media sources (television, radio, pamphlets, fliers, posters, billboards, external bus cards, newspaper articles, and bumper stickers), including short public service announcements on radio and television and a half-hour self-help television show (major network). Given information on their impact, the electronic media components were the only ones utilized throughout the intervention. In addition to the media-based informational aspects of the intervention, a Spanish-language, culturally appropriate, self-help manual for quitting cigarette smoking was distributed free of charge.

The self-help manual was specifically developed for the intervention and extensively pretested. An initial version, *Guía Para Dejar de Fumar* (National Institutes of Health [NIH] publication No. 88-3001), was distributed between 1988 and 1992. A revised edition, *El Fumar, Un Juego Peligroso*, was distributed during 1993. The self-help manual consists of 36 full-color pages covering motivation to quit and cessation and relapse prevention techniques. The revised version added techniques for dealing with stress and topics on relapse prevention and management (currently available as *Rompa con el Vicio: Una Guía Para Dejar de Fumar*, NIH publication No. 94-3001). Throughout the manual, smokers are presented with practical suggestions for quitting and with short personal testimonials of community members that support the suggestions made in the manual. Text is kept to a minimum, and all aspects of the manual are illustrated with four-color photographs. Overall, more than 70 000 copies of the self-help manual were distributed free of charge through stores, community centers, clinics, festivals, health fairs, adult schools, and colleges, as well as through personal contact with project staff and through the mail. Because of varying staffing needs of the project and the emphasis placed on the use of electronic media, the largest number of self-help manuals were distributed between 1988 and 1991.

### Target Community

The target population of this intervention was primarily Spanish-speaking Hispanics living in or around the area of San Francisco known as the Mission District. This target area is a multiethnic, predominantly working-class neighborhood with aging two-family homes and various low-rise apartment units. The 1990 census indicated that Hispanics in San Francisco are predominantly Spanish-speaking (70% of adults preferring the use of Spanish rather than English at home); young (median age of 30.2 years compared with 35.8 years for non-Hispanic whites); of Mexican (41%), Central American (35%), and other Latin American descent (24%), with a significant proportion (60%) being foreign-born; and with moderately high levels of education (65% of Hispanic adults having finished high school compared with 90% of non-Hispanic whites) (1). The mean number of residents per household (4.2) is higher among San Francisco's Hispanics than among the population as a whole (2.3).

### Evaluation Procedures

The effectiveness of the program has been evaluated through an interrupted time-series design that included seven community-wide, cross-sectional surveys conducted over the telephone with independent random samples of Hispanics in San Francisco. The first two surveys were conducted in 1986 and in 1987 to serve as a base line for the evaluation of the program. Thereafter, similar surveys were conducted every year through 1993, with the exception of 1992 when no survey was carried out. The data reported in this article were collected in those surveys.

### Procedures

Respondents were sampled by use of a modified version of the Mitofsky-Waksberg method for random-digit dialing (23). This sampling procedure reduces the number of unproductive dialings, while maintaining equal probability of selection for all telephone numbers, and has been shown to be effective with Hispanics (24). A household was judged to be eligible if the respondent identified himself or herself as Hispanic or identified the majority of the residents in the household as Hispanics. Within a given household, one Hispanic respondent was selected by asking for the resident who had most recently celebrated a birthday and who was between 18 and 65 years of age. Bilingual interviewers conducted the survey in the language preferred by the respondent. In general, 75%-80% of the respondents of each survey preferred to answer the survey in Spanish.



## Instrument

Each of the surveys included items measuring the respondents' current and past smoking behavior, the number of quit attempts in the 12 months prior to the survey, and whether they had been asked to quit in that period. Respondents in each of the surveys were asked to report (a) their awareness of the availability of smoking-cessation printed materials specifically designed for Hispanics as well as the presence of smoking-cessation groups open to Latinos; (b) if in the 30 days prior to the survey, they had heard of a program to help Hispanics quit smoking; and (c) from 1988 on, specific questions about awareness of the PLDF.

The items were translated into Spanish by use of the double-translation approach, and the English and Spanish versions were modified so that they were similar to each other (25). The Spanish version of the questionnaires was written in "broadcast Spanish" and was thoroughly pretested so as to avoid parochial meanings or misunderstanding due to regional variations in the use of Spanish (26).

In addition to standard demographic questions, a valid and reliable acculturation scale was included (27). This scale consisted of items assessing respondents' preferred language (English, Spanish, or a mixture of both) when reading and speaking, when thinking, when at home, and when with friends. Respondents answered each item on a 5-point Likert-type scale, and the responses for all four items were averaged (possible range of 1-5). Those respondents scoring 1 to <3 were categorized as low in acculturation; those scoring 3-5 were considered highly acculturated.

## Data Analysis

All data reported here are presented in terms of proportions. The intervention outcome variables were prevalence of current smoking, prevalence of cessation or "quit ratio" (proportion of ever smokers who are former smokers at the time of interview), awareness of a program to help Hispanic smokers quit, awareness of the project's name in Spanish, awareness of printed information to help Latino smokers quit, awareness of smoking cessation groups for Latinos, having a copy of the *Guía Para Dejar de Fumar*, and, among smokers, being asked to quit smoking in the previous 30 days.

Logistic regression models were constructed for each of the intervention outcome variables to ascertain the role of sex (men = 1 or referent group), education

(<12 years of formal education = 1), acculturation score (low acculturation = 1), and time of the survey as predictor variables. These models examined the intervention outcome variables for each of the cross-sectional surveys. The acculturation level of the respondents was included in the analyses because we expected to observe greater changes among the less acculturated (primarily Spanish-speaking) Latinos in San Francisco, since they were the target of the intervention and the majority of intervention strategies were presented only in Spanish. Statistically significant ORs and corresponding standard error (SE) terms are reported. Detailed results of the logistic regressions can be obtained from either author.

## Results

### Respondents

Table 1 summarizes the demographic characteristics of the individuals surveyed in each of the seven cross-sectional surveys. The independent samples were similar across surveys in their sociodemographic characteristics. The sample was limited to those between 18 and 65 years of age, and a relatively small proportion of the respondents reported being over 50 years of age. Approximately 60% of each of the samples reported having 12 or more years of formal education; in general, 60%-70% of the respondents indicated having worked for the previous 2 weeks. The majority of the sample in each of the surveys reported being foreign-born, and most individuals reported one of the Central American countries as being their place of birth. At least half of each of the samples interviewed scored low in acculturation, with approximately 20% of the sample having lived in the United States for less than 5 years. While the less acculturated respondents could be expected to answer the survey in Spanish, there are differences in the proportion of less accul-

**Table 1.** Demographic characteristics of independent cross-sectional random samples of San Francisco Hispanics, 18-65 years of age, 1986-1993\*

Characteristic	Year of survey						
	1986	1987	1988	1989	1990	1991	1993
Total No. of subjects	1660	2053	1965	1989	1959	2110	1501
% men	43.7	41.7	41.0	42.4	43.2	42.2	43.5
Age, %							
18-29 y	37.3	37.1	37.4	35.6	36.0	36.7	39.9
30-49 y	45.3	45.7	45.2	44.5	43.8	45.8	44.0
50-65 y	17.4	17.2	17.4	19.9	20.2	17.5	16.0
Education, %							
0-11 y	36.9	37.1	35.1	43.1	42.2	38.8	32.0
12-20 y	63.1	62.9	64.9	56.9	57.8	61.2	68.0
Birthplace, %							
United States	30.9	30.2	27.2	21.9	21.4	22.5	29.4
Mexico	19.8	19.6	20.9	22.1	25.8	24.8	24.3
Central America	41.9	42.3	44.9	48.0	43.1	43.6	35.5
Other Latin American countries	7.4	7.9	7.0	8.0	9.7	9.1	10.8
% with < 5 y in United States	21.4	20.2	22.4	24.8	26.9	28.9	22.3
Low acculturation, %	54.7	57.1	59.2	65.6	65.0	64.4	55.2
% responded in Spanish	66.5	69.0	70.0	80.1	81.2	78.2	50.0
% employed	NA	NA	64.2	64.9	69.6	70.0	62.4
Income, %							
<\$10 000	NA	21.3	19.4	20.7	13.9	12.2	17.7
\$10 000 to \$25 000	NA	54.0	54.7	53.0	36.0	31.3	31.3
>\$25 000	NA	24.7	26.0	26.3	50.1	56.5	51.0

\*NA = not available.

turated respondents and the proportion of individuals who chose to answer the survey in Spanish. In 1993, for example, 50% of the respondents answered in Spanish and 55.2% of the participants in the survey were classified as low in acculturation. This difference can be the result of bilingual individuals wishing to answer in English despite their relatively low level of overall acculturation. Overall, the samples showed a major increase in reported income as of the 1990 survey compared with previous surveys. These income differences are difficult to explain in the absence of more complete sociodemographic information on community residents, although it should be of little consequence to the results of this study because all services were provided free of charge.

### Prevalence of Cigarette Smoking and of Smoking Cessation

Data presented in Table 2 show the prevalence of current smokers and the prevalence of smoking cessation (often labeled "quit ratio") separately for each of the survey years by sex and acculturation level of the respondents. Overall, the samples of Hispanic respondents interviewed showed a decrease in the prevalence of cigarette smoking from a high of 24.5% in 1986 (before the beginning of the intervention) to lows of 16.0% in 1990 and 16.4% in 1991. Nevertheless, there was an increase in the prevalence of cigarette smoking between the 1991 survey and the last survey in 1993 (18.0%), and this increase was observed among both men and women. As expected, the largest net decrease in cigarette-smoking prevalence was found among the less acculturated respondents (from 24.8% in 1986 to 14.5% in 1993). This decrease of approximately 41.5% in the cigarette-smoking prevalence among the less acculturated during the 8 years of the project contrasts with the decrease of approximately 7.5% among the highly acculturated Latinos in San Francisco.

The data in Table 2 also show that there was an increase in the prevalence of cessation (proportion of ever smokers who report being former smokers at interview time) among Latinos in San Francisco. This increase in the prevalence of cessation

was observed primarily among the less acculturated who had a prevalence of cessation of 39.8% in 1986 and of 55.5% in 1993. The increase in the prevalence of cessation seems to have been greater among women (from 50.0% in 1986 to 54.6% in 1993) than among men (from 43.8% in 1986 to 46.3% in 1993).

### Awareness of Smoking-Cessation Program for Hispanics

Table 3 presents the proportion of respondents who indicated having become aware of a smoking-cessation program for Latinos during the previous 30 days. Table 3 shows that there was an increase in the awareness on the part of the respondents of group-specific cessation services from a low of 18.5% in 1986 to a high of 45.1% in 1993. This increase was found among men (from 16.3% in 1986 to 45.1% in 1993) as well as among women (from 20.2% in 1986 to 45.1% in 1993). The increase in awareness also was found among the less acculturated (from 26.1% in 1986 to 45.6% in 1993) as well as among the highly acculturated (from 9.1% in 1986 to 43.5% in 1993).

When the respondents were classified in terms of their cigarette-smoking behavior, current smokers showed an increase in awareness (from 12.6% in 1986 to 43.3% in 1993). This increase was equivalent to the rates of awareness found among former smokers (from 17.7% in 1986 to 42.2% in 1993) and among never smokers (from 21.4% in 1986 to 45.8% in 1993).

The results of the logistic regression analysis showed that there was a statistically significant increase in awareness of a smoking-cessation program for Latinos among the less acculturated (OR = 3.95; SE = 0.05;  $P < .001$ ), those with less than 12 years of formal education (OR = 1.19; SE = 0.04;  $P < .001$ ), and among women (OR = 0.88; SE = 0.04;  $P < .01$ ). More importantly, the passing of time significantly influenced the level of awareness reported by the respondents (OR = 1.11; SE = 0.01;  $P < .001$ ) during the 7 years of the surveys.

From 1988 through 1993, respondents were asked to report if they were aware of the existence of the PLDF. Table 3 shows the proportion of respondents who reported being aware of the

**Table 2.** Prevalence (%) of cigarette smoking and of smoking cessation by sex and acculturation among San Francisco Hispanics, 18-65 years of age, 1986-1993

Characteristic	Year of survey						
	1986	1987	1988	1989	1990	1991	1993
Total No. of respondents	1660	2053	1965	1989	1959	2110	1501
<i>Prevalence of smoking, % current smokers</i>							
All	24.5	21.2	21.4	17.4	16.0	16.4	18.0
Sex							
Men	33.8	27.0	28.7	24.6	23.4	23.1	25.1
Women	17.3	17.1	16.3	12.1	10.4	11.5	12.6
Acculturation							
Low	24.8	20.3	18.9	15.3	14.2	13.3	14.5
High	24.1	22.6	25.0	21.4	19.5	21.8	22.3
<i>Prevalence of smoking cessation, % ever smokers who are former smokers</i>							
All	44.7	50.1	45.3	52.4	52.9	51.7	50.1
Sex							
Men	43.8	51.2	45.9	49.8	50.3	51.4	46.3
Women	50.0	48.7	44.6	55.9	56.9	52.1	54.6
Acculturation							
Low	39.8	50.1	46.5	54.3	54.4	56.5	55.5
High	49.9	50.0	44.0	49.9	50.7	45.2	44.7



**Table 3.** Awareness of a smoking-cessation program for Hispanics by sex, acculturation, and smoking status among San Francisco Hispanics, 18-65 years of age, 1986-1993\*

Characteristic	Year of survey						
	1986	1987	1988	1989	1990	1991	1993
Total No. of respondents	1660	2053	1965	1989	1959	2110	1501
<i>% aware of a smoking-cessation program for Hispanics</i>							
All	18.5	21.9	35.8	43.2	32.5	30.5	45.1
Sex							
Men	16.3	18.0	31.0	42.8	30.5	29.2	45.1
Women	20.2	24.7	39.2	43.5	34.0	31.4	45.1
Acculturation							
Low	26.1	30.4	51.8	55.1	42.4	39.9	45.6
High	9.1	10.8	12.8	20.7	14.1	13.4	43.5
Smoking status							
Current smoker	12.6	15.3	31.7	35.8	31.4	22.0	43.3
Former smoker	17.7	22.7	29.9	46.1	30.1	29.7	42.2
<i>% aware of the Programa Latino Para Dejar de Fumar</i>							
All	NA	NA	32.4	48.3	44.4	49.8	41.7
Sex							
Men	NA	NA	27.5	45.6	40.9	46.7	38.4
Women	NA	NA	35.8	50.3	47.1	52.1	44.2
Acculturation							
Low	NA	NA	45.9	62.2	57.3	64.0	62.0
High	NA	NA	12.8	21.8	20.7	24.0	16.7
Smoking status							
Current smoker	NA	NA	29.8	42.5	41.5	39.9	34.2
Former smoker	NA	NA	29.1	51.5	40.6	48.9	39.6

\*NA = not available.

program by its name. Overall, there was an increase in awareness for all of the respondents from an initial rate of awareness of 32.4% in 1988 (approximately 1 year after the PLDF interventions started) to 41.7% in 1993. The increase in awareness was found among men (from 27.5% in 1988 to 38.4% in 1993) as well as among women (from 35.8% in 1988 to 44.2% in 1993). Less acculturated Hispanics showed a higher increase in awareness (from 45.9% in 1988 to 62.0% in 1993) than those who scored high in acculturation (from 12.8% in 1988 to 16.7% in 1993). The increase in awareness was also found among current smokers (from 29.8% in 1988 to 34.2% in 1993) and among former smokers (from 29.1% in 1988 to 39.6% in 1993).

The results of the logistic regression analysis showed that there were statistically significant increases in awareness of the PLDF among less acculturated respondents (OR = 5.40; SE = 0.05;  $P < .001$ ), respondents with less than a high school education (OR = 1.28; SE = 0.05;  $P < .001$ ), and women (OR = 0.84; SE = 0.05;  $P < .001$ ) and that the passing of time increased the level of awareness (OR = 1.14; SE = 0.02;  $P < .001$ ) during the time of the intervention.

#### Awareness of Actual Smoking-Cessation Services for Latinos

There was an increase in the awareness of the availability of smoking-cessation printed information targeting Latinos, from 41.8% in 1986 to 48.7% in 1993 (Table 4). The increase in awareness occurred among men (from 35.5% in 1986 to 46.3% in 1993) but not among women (from 51.2% in 1986 to 50.6% in 1993). The largest increase in reported awareness was found

among the less acculturated Hispanics (from 30.0% in 1986 to 40.8% in 1993) compared with the more acculturated Hispanics (from 56.4% in 1986 to 58.8% in 1993). The data also showed an increase in the reported awareness of smoking-cessation printed materials on the part of current cigarette smokers (from 41.8% in 1986 to 58.6% in 1993).

The results of the logistic regression analysis showed that the level of awareness of the availability of printed smoking-cessation information for Hispanics increased among the more acculturated respondents (OR = 0.63; SE = 0.05;  $P < .001$ ), among those with more than a high school education (OR = 0.70; SE = 0.05;  $P < .001$ ), and among women (OR = 0.78; SE = 0.04;  $P < .001$ ) and that awareness increased significantly with the passing of time (OR = 1.09; SE = 0.01;  $P < .001$ ).

Respondents were also asked to report their awareness of the availability of smoking-cessation groups for Hispanics. There was minimal change in awareness of smoking-cessation groups (from 26.4% in 1986 to 27.2% in 1993) among respondents (Table 4). Men showed an increase in awareness between 1986 (25.0%) and 1993 (26.0%), while women reported a slight decrease in awareness (28.4% in 1986 to 28.1% in 1993). The less acculturated showed an increase in awareness from 13.2% in 1986 to 20.9% in 1993, while the more acculturated actually showed a decrease in awareness (from 43.3% in 1986 to 35.1% in 1993). Current smokers showed an increase in awareness of cessation groups (from 26.6% in 1986 to 34.6% in 1993).

The results of the logistic regression analysis showed that there were statistically significant increases in the awareness of the availability of smoking-cessation groups among more accul-

**Table 4.** Awareness of smoking-cessation services by sex, acculturation, and smoking status among San Francisco Hispanics, 18-65 years of age, 1986-1993\*

Characteristic	Year of survey						
	1986	1987	1988	1989	1990	1991	1993
Total No. of respondents	1660	2053	1965	1989	1959	2110	1501
<i>% aware of printed information to help Latino smokers quit</i>							
All	41.8	42.4	36.4	44.5	44.5	47.2	48.7
Sex							
Men	35.5	38.0	35.9	43.4	39.7	42.5	46.3
Women	51.2	47.3	36.7	45.3	48.2	50.5	50.6
Acculturation							
Low	30.0	30.8	30.6	41.2	40.1	42.6	40.8
High	56.4	56.7	44.7	50.7	52.8	55.5	58.8
Smoking status: current smoker	41.8	42.3	45.2	52.5	51.4	54.3	58.6
<i>% aware of smoking-cessation groups for Latinos</i>							
All	26.4	33.6	17.1	19.2	19.0	19.2	27.2
Sex							
Men	25.0	28.8	16.8	18.3	17.5	17.7	26.0
Women	28.4	38.9	17.3	19.8	20.2	20.3	28.1
Acculturation							
Low	13.2	24.9	13.1	16.0	13.5	14.7	20.9
High	43.3	44.3	22.8	25.0	29.3	27.4	35.1
Smoking status							
Current smoker	26.6	33.5	23.2	24.1	22.7	22.3	34.6
Former smoker	NA	50.0	22.8	22.6	21.4	20.8	26.0
<i>% reported having a copy of the Guía Para Dejar de Fumar</i>							
All	NA	NA	7.5	19.7	14.6	16.5	9.2
Sex							
Men	NA	NA	5.9	19.1	12.9	15.5	7.0
Women	NA	NA	8.6	20.2	15.9	17.3	10.9
Acculturation							
Low	NA	NA	10.8	26.1	19.3	21.8	12.1
High	NA	NA	2.6	7.6	6.0	7.1	5.7
Smoking status							
Current smoker	NA	NA	10.5	24.6	17.3	20.5	7.6
Former smoker	NA	NA	7.8	20.5	15.3	18.1	7.2

\*NA = not available.

tured respondents (OR = 0.54; SE = 0.05;  $P < .001$ ), among more educated Latinos (OR = 0.60; SE = 0.06;  $P < .001$ ), and among women (OR = 0.85; SE = 0.05;  $P < .001$ ). However, the passing of time (OR = 1.02; SE = 0.06; not significant) was not a significant predictor of awareness of cessation groups.

In the surveys conducted between 1988 and 1993, all respondents were asked if they had a copy of the self-help manual produced by the project (*Guía Para Dejar de Fumar*). There was an increase in the proportion of respondents reporting actual possession of a copy of the self-help manual, from 7.5% in 1988 to 9.2% in 1993 with a high of 19.7% in 1989, when a significant portion of the staff efforts was dedicated to the free distribution of the manual. The increase in ownership of the self-help manual was found among men (from 5.9% in 1988 to 7.0% in 1993) as well as among women (from 8.6% in 1988 to 10.9% in 1993). The increase was also found among the less acculturated (from 10.8% in 1988 to 12.1% in 1993) and among the more acculturated (from 2.6% in 1988 to 5.7% in 1993).

The results of the logistic regression showed that there were statistically significant increases in the rate of reported ownership of the self-help manual among the less acculturated respondents (OR = 4.54; SE = 0.08;  $P < .001$ ) and across the years of the project surveys (OR = 1.09; SE = 0.20;  $P < .001$ ). There were no significant differences in ownership of the *Guía Para Dejar*

*de Fumar* by the respondents' educational level (OR = 1.02; SE = 0.06; not significant) or by sex (OR = 0.89; SE = 0.06; not significant).

### Experiences of Pressure to Quit Smoking

During each of the surveys, respondents who reported being current smokers were asked to report if someone had asked them to quit smoking during the 30 days prior to the survey (Table 5). There was an increase in the proportion of smokers reporting being asked to quit (from 39.8% in 1986 to 63.0% in 1993). The increases were observed among men (from 38.2% in 1986 to 62.2% in 1993), women (from 42.1% in 1986 to 64.4% in 1993), the less acculturated (from 43.9% in 1986 to 64.7% in 1993), and the highly acculturated (from 34.1% in 1986 to 61.2% in 1993).

Logistic regression analysis showed that smokers were significantly more likely to be asked to quit smoking if they had a low acculturation level (OR = 1.28; SE = 0.09;  $P < .01$ ), if they had less than a high school education (OR = 1.30; SE = 0.09;  $P < .01$ ), and if they were women (OR = 0.66; SE = 0.09;  $P < .001$ ). This effect also increased with the passing of time (OR = 1.26; SE = 0.02;  $P < .001$ ).



**Table 5.** Percent of current smokers asked to quit smoking during the 30 days prior to the survey by sex and acculturation, San Francisco Hispanics, 18-65 years of age, 1986-1993

	Year of survey						
	1986	1987	1988	1989	1990	1991	1993
Total No. of smokers	407	435	421	346	313	346	270
All	39.8	41.4	46.1	47.7	67.7	67.8	63.0
Sex							
Men	38.2	36.2	42.9	42.7	65.0	60.5	62.2
Women	42.1	47.3	50.0	55.1	72.4	78.6	64.4
Acculturation							
Low	43.9	47.3	49.8	51.5	67.4	68.9	64.7
High	34.1	34.5	42.0	42.1	68.2	66.5	61.2

## Discussion

In developing the PLDF, we elected to implement a community intervention to decrease cigarette-smoking prevalence because we concluded that a public health model was the most effective way to reach smokers, even if successful cessation may be lower than with clinical interventions. Basic to the development of the intervention was the belief that its acceptability and effectiveness would be enhanced if it incorporated the basic components of a culturally appropriate intervention: (a) culture-specific beliefs and values; (b) group-specific attitudes, norms, and expectancies; and (c) appropriate intervention channels and sources (16).

The components of the PLDF were developed on the basis of observed differences and similarities between Latino and non-Hispanic white smokers. The intervention strategies of the program were consistent with central Latino cultural values (e.g., familism and *simpatía*). In addition, the messages were tailored to emphasize the attitudes and expectancies that previous basic research had shown to be perceived as the major motivators of Hispanic smokers to quit (e.g., concern over the health of children, worry about bad breath produced by smoking, and not providing a bad example to children) (8-12). Cessation techniques and strategies were included in all program messages only after formative research had shown that they were perceived as credible and effective cessation approaches by Hispanic smokers. Furthermore, the program used information sources (e.g., physicians and community leaders) and channels (radio and television) that formative research had shown to be perceived as credible, disinterested, and as motivating behavioral change (7,28,29). Since the program targeted the less acculturated Latinos in San Francisco, all intervention materials and strategies were presented in Spanish (Table 6).

The program and its evaluation were designed with the belief that changes in awareness of the existence of the PLDF and its various messages and services would precede any effects on cigarette-smoking prevalence. The data presented above show that the program's activities were related to changes in prevalence of cigarette smoking and of cessation as well as to changes on such mediating variables as awareness of the program and of information about access to cessation interventions. These data extend our earlier findings that the community intervention has been effective in disseminating smoking-cessation information in the San Francisco Latino community (7,20).

Awareness of a smoking-cessation program for Hispanics more than doubled from 1986-1987 to 1993, and the increase was noted in both men and women, among the more and less acculturated Hispanics, and among current and former smokers. However, the yearly changes were not consistent, and 1989 appeared to represent a peak effect, especially among less acculturated Hispanics. Subsequently, awareness levels waned until the most recent survey in 1993, when all Hispanics reported similar levels of awareness. Specific awareness of the PLDF by name also peaked in 1989 but was more consistent in ensuing surveys. The fact that 64% and 62% of less acculturated Latinos (compared with 24% and 17% of more acculturated Latinos) were aware of the PLDF name in 1991 and 1993, respectively, is most likely a result of this intervention conducted exclusively in Spanish. The California Tobacco Education Program, which was implemented in 1991 with a statewide media campaign and numerous smoking-cessation activities, may account for the marked increase in awareness among more acculturated Hispanics in 1993.

The proportion of Latinos who reported being aware of printed information to help smokers quit increased gradually from 1986 to 1993. Women, more acculturated respondents, more educated Latinos, and current smokers were significantly more likely to be aware of cessation printed information during the 7-year period. By comparison, awareness of cessation groups varied considerably more among Latinos, although women, more acculturated individuals, more educated persons, and current smokers reported significantly increased awareness. The PLDF did not offer cessation groups after 1990; thus, these effects may be the result of services offered by the public hospital and the services provided by the voluntary associations in English.

The *Guía Para Dejar de Fumar*, however, was specifically distributed by the PLDF, and the results showed a peak effect in 1989-1991 and a considerable drop-off in 1993. During 1989-1991, greater efforts were made at mass distribution of the self-help manual published by the National Cancer Institute. Subsequently, the PLDF made selected distribution of the second edition of the manual entitled *Fumar. . . Un Juego Peligroso* with a different cover photograph and moderate revisions in the content. It is possible that respondents were confused as to what was meant by the cessation self-help manual, even though interviewers explained that there were two editions. The

**Table 6.** Percent of respondents who received information about the PLDF through different media channels by sex and acculturation, San Francisco Hispanics, 18-65 years of age, 1988-1993

	Year of survey				
	1988	1989	1990	1991	1993
Total No. of respondents	1965	1989	1959	2110	1501
<i>% respondents received information from pamphlet or booklet</i>					
All	32.9	41.2	42.9	46.9	61.5
Sex					
Men	28.2	40.2	42.6	44.0	60.6
Women	36.1	42.0	43.2	49.1	62.1
Acculturation					
Low	41.3	50.8	52.3	59.0	62.7
High	20.6	22.9	25.7	25.5	56.8
Smoking status: current smoker	28.5	38.0	44.7	44.2	54.4
<i>% respondents received information from radio</i>					
All	43.7	48.5	49.8	49.1	67.2
Sex					
Men	39.6	46.8	50.1	45.8	72.3
Women	46.6	49.7	49.6	51.4	63.8
Acculturation					
Low	60.8	63.6	64.3	63.4	72.9
High	18.7	19.5	23.3	22.9	41.3
Smoking status: current smoker	36.9	42.3	45.2	41.6	65.3
<i>% respondents received information from television</i>					
All	49.9	56.6	65.0	64.5	85.8
Sex					
Men	45.0	54.4	61.7	61.7	86.6
Women	53.4	58.3	67.5	66.4	85.2
Acculturation					
Low	63.2	70.2	79.3	80.5	91.3
High	30.5	30.9	38.9	35.6	59.5
Smoking status: current smoker	43.4	48.4	59.1	55.5	78.4

second edition of the manual was also available for distribution by any other agency or program that requested it from the State of California Health Department. In addition, the variation in rates of having the self-help manual may be due partly to sample variability. While ownership of the self-help manual does not imply having read it, data are not currently available on the proportion of community members who read the self-help manual. An unpublished study evaluating the effectiveness of the second edition of the self-help manual showed that a large proportion of individuals who have the manual have read it. Furthermore, in an evaluation of the *Guía Para Dejar de Fumar* among Latino smokers, a majority recalled specific photographs or aspects of the manual (30).

Our data show evidence that the community norms about cigarette smoking evolved among San Francisco Latinos. The proportion of Latino smokers asked to quit smoking increased to more than 60%. Although women, less acculturated smokers, and those with fewer years of education were more likely to be asked to quit, this effect was observed in all groups. We specifically promoted messages to nonsmokers to help a smoker quit; thus, the PLDF intervention may have been partially responsible for these effects.

Although the purpose of this article was to focus on disseminating information about smoking cessation, the outcome of greatest interest is cigarette-smoking prevalence. Cigarette-smoking rates appeared to decrease in San Francisco's Latino

community during most of the 7-year period of the study, but limitations in our study design do not allow any definite conclusions about direct causal effect. We did not survey a control community with a comparable sample of Latinos living in an urban area not receiving this type of community intervention. Thus, we can compare only smoking rates to the two base-line surveys in an interrupted time-series design, which greatly limits our ability to conclude that the PLDF contributed to the overall decrease in prevalence. In an extensive analysis of the first four annual surveys, we concluded that the PLDF had significant effects on mediating variables that may over a longer period result in smoking cessation (21). A future report will analyze these data to further evaluate possible effects on cigarette-smoking prevalence.

As with any community intervention, experiences with the development and implementation of the PLDF showed the problems faced by massive interventions when limited by financial and personnel resources. Distribution of the self-help manual relied heavily on the goodwill of store owners and health care personnel who at times failed to provide proper display space or to hand out the manual to Latino smokers. While we were able to pay for placement of some radio and television messages, a proportion of the messages was presented in public service slots that frequently included times when few viewers or listeners were available. The evaluation of the intervention was also limited by the fact that we needed to rely on self-reports as part



of community surveys that may have been affected by acquiescence and extreme response sets (31). In addition, statewide initiatives, such as the increase in sales tax on cigarette packs and the ensuing tobacco control campaign, may have affected the results of the intervention in its final years.

In conclusion, we have documented that a culturally appropriate community intervention to promote cigarette-smoking cessation can be successful at disseminating information. Maintenance of these efforts requires a continuous renewal of strategies and specific components that can be evaluated. Nevertheless, the experiences of the PLDF have shown that a culturally appropriate community intervention can produce dramatic changes in information and community norms. The changes in information reported here are larger than what could be expected of community interventions that, by their nature, produce minor modifications in people's information levels. While the lack of a control community in the design of the study limits the strength of the conclusions that can be reached from our data, it can easily be assumed that the development of culturally appropriate interventions will actually augment the effectiveness of community interventions.

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## Notes

<sup>1</sup>The terms "Hispanic" and "Latino" are used interchangeably here to denote individuals whose background can be traced to one of the Spanish-speaking countries of the Americas.

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# Hispanic Research: Implications of the National Institutes of Health Guidelines on Inclusion of Women and Minorities in Clinical Research

*Carlos E. Caban\**

Researchers have new opportunities to increase Hispanic health research as a result of the requirements in the March 1994 National Institutes of Health (NIH) guidelines on inclusion of women and minorities (and their subpopulations) as subjects in the biomedical and behavioral research projects that NIH supports. These guidelines are summarized and their implications for research are discussed here. Investigators must include women and minorities in their research involving human subjects and also present outreach plans for recruitment and retention of Hispanic and other participants into this clinical research. When clinical trials are planned, they need to be designed to measure differences in intervention effect in subpopulations when warranted. Investigators are challenged to develop new studies to fill the gaps in our knowledge about how racial/ethnic/cultural factors affect health and disease in Hispanic subgroups. This knowledge is necessary for designing studies that are culturally sensitive, enroll appropriate numbers of Hispanic participants, and ensure that the benefits of the research are made available to the Hispanic community. [Monogr Natl Cancer Inst 18:165-169, 1995]

## Status of Research on Hispanic Health

Hispanics have been underrepresented in research for many years. This was documented in a 1985 Department of Health and Human Services (DHHS) Report of the Secretary's Task Force on Black and Minority Health (1), which had gaps in data on Hispanics and their major subgroups (Mexican-American, Cuban-American, and Puerto Rican). Recommendations in the report included improving and fully using available sources of data (recommendation 7) and adopting and fostering a research agenda to investigate factors affecting minority health (recommendation 8).

The special issues relating to Hispanics have been reported in the scientific literature, including the deficiencies in the data. Marín and Marín (2) provided a comprehensive review of the issues involved in doing research with Hispanic populations on the basis of their demography, heterogeneity, cultural values, and language; they described the special methodologic challenges in obtaining valid research results when research involves Hispanics. The lack of Hispanic data in 21 major DHHS health data systems was recently described by Delgado and Estrada

(3). Molina and Aguirre-Molina (4) present a recent comprehensive description of Hispanic/Latino health status that includes chapters on demography (5); the influence of culture, class, and the environment on health care (6); and specific diseases, including cancer (7). Within DHHS, a comprehensive set of recommendations was made to the Surgeon General to improve Hispanic/Latino health as a result of the Surgeon General's National Hispanic/Latino Health Initiative (8).

Additional reports on cancer in Hispanics are presented in this monograph and include the epidemiology of cancer in Hispanics by Trapido et al. (9) and the impact of Hispanic diversity on cancer prevention and control by Ramirez et al. (10). Suarez and Pulley (11) provide an excellent example of research tailored for Hispanics through the use of acculturation scales.

Although a recent bibliography (12) of the scientific literature on Hispanic-American health, which includes 1799 citations from January 1990 through July 1994, demonstrates the growing interest in research with Hispanic populations, there remain major gaps in understanding the similarities and differences in health and disease between the Hispanic subgroups as well as between Hispanics and other racial and ethnic groups. In reviewing the literature, many articles compare whites with blacks, with minorities as a group, or with blacks and other minorities; it becomes clear that Hispanics have not been systematically included in research when compared with non-Hispanic whites.

One means of monitoring health status is through the national health promotion and disease prevention objectives for the year 2000 (13). However, the absence of meaningful data on Hispanics cited above was reflected in the limited number of objectives related specifically to Hispanic health issues.

## Development of the National Institutes of Health (NIH) Guidelines

The 1985 DHHS report (1) was the impetus for developing National Institutes of Health (NIH) policies and guidelines to in-

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See "Note" section following "References."



crease the representation of women and minorities in research study populations. The implementation of the initial 1986 NIH and Alcohol, Drug Abuse, and Mental Health Administration policies was criticized in a 1990 General Accounting Office report, which stated that women were still routinely excluded from NIH-supported research studies and that the policy itself had not been adequately communicated. The resulting outcry from the public and the Congress led NIH to respond by reiterating and strengthening the existing policies for inclusion of women and minorities; by publishing the revised policies in the NIH Guide for Grants and Contracts (14,15); by conducting a broad educational program for NIH staff, peer reviewers, and advisory councils and boards; and by revising the instructions and forms for applying for NIH grants and contracts.

Congressional interest continued, with the inclusion requirement codified into law in the 1993 NIH Revitalization Act (P.L. 103-43), resulting in the publication of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (16) in March 1994 and, subsequently, an "Outreach Notebook" (17) and a "Questions and Answers" document (18), which provide further guidance on implementation of the policy. A broad educational and dissemination program has been implemented concerning the new guidelines, with orientation and training efforts for NIH advisory councils and boards, initial review groups (including the NIH study sections), NIH staff, and professional organizations.

Key elements of the guidelines are summarized below. However, investigators should read all three documents (16-18) to fully understand the guidelines and their implications when developing their applications and proposals for research projects supported by NIH. Specific information and instructions on how to address the guideline requirements are found in the "Questions and Answers" document (18), in the Application for Public Health Service grant (Form 398), and in individual Requests for Proposals (RFPs) issued by NIH.

## NIH Guidelines

NIH guidelines state the following (16):

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

In addition, the new guidelines discuss the "NIH-defined Phase III Clinical Trial," the requirement for outreach programs to recruit women and minorities and their subpopulations into clinical studies, and the requirement for peer review of projects.

## Clinical Research

The intent of the guidelines is to understand the implications of research findings on gender and minority group and minority subpopulations. A broad definition is used for clinical research: all research involving human subjects is defined as clinical research. Because of the gaps in basic knowledge about minorities, and especially Hispanics (1), investigators need to include them beginning at the earliest stages of research so that information can be systematically obtained and evaluated about the relationship between the specific subpopulations, the disease under study, and corresponding interventions and to identify any differential effects by sex or minority group. This is especially important as new surveys are designed and previous surveys are repeated and expanded (3). Culturally sensitive research methods, materials, and data-collection instruments are needed in the design and implementation of these research projects (2) to ensure that factors such as language, education, health beliefs and customs, and access to health care are appropriately addressed (6).

One issue is what proportion of each minority group should be included in the study population and what denominator to use in determining this proportion. It is not anticipated that every study will include all minority groups and subgroups. The inclusion of minority groups should be determined by the scientific questions under examination and their relevance to racial/ethnic groups. Applications should describe the subgroups that will be included in the research.

The investigator should address inclusion issues in terms of the size of the study; the relevant characteristics of the disease, disorder, condition, or phenomena under study; or the feasibility of making a collaboration or consortium or other arrangements to include representation. Information on the national and local population demographics is important in planning the study. Exclusion of any group should be based on science, and not for the convenience of the investigator. Single clinic or hospital studies should be viewed, optimally, in terms of the national or broader regional or community demographics of the disease or condition to avoid selection bias due to local clinic or hospital enrollment. In some cases, multicenter studies may be established to meet the general inclusion requirements by combining recruitment from multiple sites, with the opportunity for institutions with high minority recruitment to become partners in the research effort. Study designs involving oversampling may also be appropriately justified.

Specific studies on Hispanics and their subgroups are allowed within the NIH policy, in addition to studies including several racial/ethnic populations. There must be a scientifically acceptable justification, however, for limiting the study to only one sex or minority group, such as high prevalence of the condition, unique disease characteristics, or gaps in knowledge in the selected population. Recent research has included a number of studies on Hispanics and their subpopulations (12); however, a recent review (7) points to the limitations in our knowledge and the need for more cancer control research in Hispanic communities and for better reporting and dissemination of research results. Thus, this area will benefit from more targeted research addressing the Hispanic subpopulations.



## NIH-Defined Clinical Trials

NIH has developed a special definition for clinical trials as used in its policy (16) to distinguish these trials from the other types of clinical research that NIH supports and from other definitions, e.g., by the Food and Drug Administration. These clinical trials are an important subset of all clinical research projects.

For the purposes of the NIH policy, an NIH-defined clinical trial is a broadly based prospective phase III clinical investigation that is designed to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. This emphasis on the impact of the trial in changing policy or practice is a key feature distinguishing these trials from other clinical research.

When planning these clinical trials, investigators must review the available evidence to show whether or not clinically important gender or race/ethnicity differences in response to the intervention are to be expected based on prior investigations. Thus, the inclusion of minorities, such as Hispanic subgroups, in the earlier research would provide critical information on any such expected differences as well as the degree of participation required in the new clinical trial. Depending on the evidence, the clinical trial may need to be designed for valid analysis, with high statistical power, of the intervention effect in these subpopulations (16). At this time, it is too early to determine the impact of these guidelines on new clinical trials; this will be tracked as new studies are undertaken (*see below*).

## Ethical Issues

Ethical issues need to be considered and handled appropriately when developing and implementing outreach plans for recruitment and retention of participants, especially minorities such as Hispanics, and these issues are discussed in the Outreach Notebook (17) and OPRR Reports (19). Investigators, their staff, and local Institutional Review Boards (IRBs), which review all studies involving human subjects, must ensure that participation is voluntary and based on adequate information (informed consent), that benefits outweigh risks, and that no group is denied benefit without good reason.

The inclusion of both women and men and of minorities in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. To the extent that participation in research offers direct benefits to the participants, underrepresentation of men, women, or minorities denies them the opportunity to receive this benefit. Moreover, for purposes of generalizing research results, investigators must include the widest possible range of population groups.

As part of this process, the NIH requirement for inclusion of minorities, such as Hispanics and their subgroups that are economically or educationally disadvantaged, should be dealt with in a manner that does not lead to undue pressure on or

coercion of individuals to participate, e.g., for economic reasons to receive reimbursement.

When participants prefer another language, e.g., Spanish, the informed consent process and documents should be available in that language and quality control procedures used, such as translation from English to the other language and then back to English, to ensure that the information is conveyed correctly. Investigators should not routinely depend on ad hoc translations without quality control. These issues are discussed by Márin and Márin (2), OPRR Reports (19), and the IRB Handbook (20).

Hispanics should be considered for membership on IRBs, especially for review of projects involving Hispanics, to ensure that the relevant culture and language are appropriately addressed in the research project, informed consent process, and outreach plans.

## Outreach

Outreach efforts to recruit and retain women and minorities in studies are now an important component of the NIH guidelines. Such efforts must be culturally sensitive and involve the target community for maximum effectiveness so that the most diverse study populations may be included consistent with the purposes of the research. Precautionary measures should be taken to avoid coercion or undue influence in the incentives or rewards offered to prospective participants when recruiting or attempting to retain participants in the studies.

To assist investigators, the NIH Outreach Notebook (17) summarizes key elements of outreach, such as understanding the study population and its culture, establishing explicit goals and working with the community, achieving agreement on research plans, designing and conducting evaluation plans, and establishing and maintaining communication with all those involved in the study as partners in research. Why these elements are important and how each should be approached are discussed, as well as the issue of evaluation of the outreach plans as part of the peer review process. The Outreach Notebook is one of many possible approaches to addressing the outreach requirements for research.

The costs of outreach efforts to improve Hispanic participation in research, such as reimbursement for expenses or bilingual staff, need to be included and justified as part of the necessary components of research. Studies of various approaches to enhancing participation are needed. Addressing these issues related to access to the health care system are critical to success, as reviewed by Giachello (21). Investigators may be concerned about the expected increased costs needed to involve the various minority groups; however, the legislation is clear that cost should not be a consideration for not including them (14).

Several examples of outreach efforts addressed specifically to Hispanic populations are reported in this monograph and demonstrate the issues and types of approaches that have been successful (22-25).



## Review Criteria

The guidelines require that the plans for inclusion of women and minorities and their subpopulations, any justifications when representation is limited or absent, the adequacy of design of clinical trials to measure differences when warranted, and the plans for recruitment/retention/outreach are to be evaluated and considered in the scientific merit score.

Thus, initial review group members look for evidence that the investigator has satisfactorily addressed the inclusion policy in the application or proposal. Such evidence may include (but is not limited to), for example, information on the population characteristics of the disease or condition under study; national and local demographics of the population; knowledge and understanding of the racial/ethnic/cultural characteristics of the population; prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied; and the plans, arrangements, and letters of commitment from relevant community groups and organizations for the planned study. Justifications should also be made in support of appropriate staffing needs for outreach plans. Exclusions of any group should be based on science, and not for the convenience of the investigator.

## Reporting on Inclusion

NIH has developed a consistent reporting format (Table 1) for investigators to use when they plan and report on progress in recruitment and retention of study participants. This format will be required in applications (using the PHS 398 application) and contract proposals and has been required for annual progress reports for projects supported by NIH since 1992. The table uses the main racial and ethnic categories defined by the Office of Management and Budget for federal reporting. Although not previously required, minority subpopulation data will now be reported as well.

In its guidelines, NIH has defined a minority group as "... a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage." Each minority group contains subpopulations that may be defined by geographic origin, national origin, cultural differences, or mixed racial and/or ethnic parentage. The minority group or subpopulation to which an individual belongs is determined by self-reporting. For illustrative purposes, the major subpopulations for Hispanics would include Mexican-American, Cuban-American, and Puerto Rican, although other examples of subpopulations may be used by investigators for their research projects.

This approach should encourage investigators to discuss the study population in terms of its gender and racial/ethnic com-

position; filling out the table format will quickly identify the gaps. Peer reviewers will also look at the discussion and composition of the population as presented in the table, the population choices, and the accompanying rationale in evaluating the proposed study and including it as part of the priority score given to the project. Progress in achieving recruitment goals will also be tracked in this manner.

During 1995, NIH will be completing development and implementation of a computerized tracking system on the basis of this reporting format for all research involving human subjects supported by NIH. For the first time, the analysis and reporting will provide NIH with a complete picture of the gender and racial/ethnic composition of the planned and enrolled participants in its research studies and the specific gaps that need to be addressed. This will more easily allow analysis of the Hispanic representation in the research portfolio of an NIH Institute, its research program, and specific diseases and will highlight where further efforts are needed. It may also stimulate broader approaches, such as meta-analyses, to evaluate many studies with low Hispanic participation for specific diseases and interventions.

## Opportunities

The new NIH guidelines provide an impetus for more opportunities for Hispanic and other researchers to address the health-research needs of Hispanics and their subgroups. Examples of opportunities to pursue include the following:

- Giving higher priority to investigator-initiated research on Hispanic and other minority health issues to meet the intent of the law.
- Targeting new initiatives to gaps in knowledge about Hispanic health as NIH addresses gaps in its research programs.
- Developing culturally sensitive and relevant methods and data collection instruments.
- Including Hispanics at all phases of research projects to obtain a systematic collection of information on Hispanics.
- Including Hispanics and their subgroups in national data systems and surveys in representative numbers or with oversampling to ensure valid results.
- Increasing opportunities for collaboration as coinvestigators on research projects to provide scientific and cultural expertise.
- Participating in multicenter trials as special centers for recruitment of Hispanics.

Table 1. NIH reporting format for gender and minority inclusion in a research study

	American Indian or Alaskan native	Asian or Pacific Islander	Black, not of Hispanic origin	Hispanic	White, not of Hispanic origin	Other or unknown	Total
Female							
Male							
Unknown							
Total							



- Ensuring appropriate informed consent for Hispanic participants in research through preparation and/or review of procedures and study documents.
- Ensuring that outreach plans appropriately include the Hispanic community when Hispanics are participants in the research.
- Empowering communities to establish better means of accessing their members into appropriate clinical research studies.
- Increasing the pool of Hispanic researchers as principal investigators on research projects.
- Seeking appropriate Hispanic representation on IRBs when Hispanic subjects are involved in research under review.
- Increasing representation in NIH peer review groups and on advisory councils and boards.

## Concluding Remarks

Researchers have new opportunities to increase Hispanic health research as a result of the requirements in the March 1994 NIH guidelines on inclusion of women and minorities and their subpopulations as subjects in the biomedical and behavioral research projects that NIH supports.

Research involving Hispanics is reaching a critical mass in terms of the number of investigators and ongoing research projects. The issues confronting Hispanic health research have been identified and characterized (1,4,8). The NIH guidelines require inclusion of Hispanics in NIH clinical research projects, and ongoing evaluation of this participation will help update the databases on Hispanic health issues and further clarify the gaps that need to be addressed.

The research literature is growing rapidly (12), with special journal issues devoted to Hispanic health, such as this Journal of the National Cancer Institute monograph, which contains 22 articles. The literature demonstrates that effective and culturally sensitive research can be done in Hispanic subgroups, that meaningful differences exist in disease and intervention effects between Hispanic subgroups and other population groups that need to be addressed in designing research projects, and that these issues can guide future research directions. The implications of the NIH guidelines present many opportunities for rapidly increasing our knowledge base and research efforts addressing Hispanic health issues so that the benefits of the research are made available to the Hispanic community.

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## Note

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## ***Correction:*** Prior Annotation of B. Fisher's Papers Incorrect

Medline, CancerLit, and PDQ erroneously annotated certain articles authored or co-authored by Dr. Bernard Fisher with the phrase "scientific misconduct—data to be reanalyzed." All such annotations have been removed or are being removed. However, the Journal published the incorrect annotation in the reference lists of papers that cited those articles. We apologize for any problems or concerns this may have caused. Readers should disregard the erroneous annotations in the papers named below:

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# **National Cancer Institute Economic Conference: the Integration of Economic Outcome Measures Into NCI-Sponsored Therapeutic Trials**

Proceedings of a Workshop  
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*National Cancer Institute Economic  
Conference: the Integration of Economic  
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# Introduction

*Mary S. McCabe, Michael A. Friedman\**

Efforts are expanding throughout the U.S. health care system to formally develop procedures to assess costs as part of the evaluation of new therapies. As a consequence, economic analyses are becoming incorporated with increasing frequency in clinical trials. Although oncologists are familiar with traditional study end points (i.e., response, survival, toxicity, functional status, and symptom reduction), the relationship between cost and expected benefits as an end point will require new theoretical and methodologic approaches. Cost-effectiveness and cost efficiencies require the consideration and utilization of medical economics expertise, which has not yet been well integrated into oncology clinical trials; indeed, few National Cancer Institute (NCI)-sponsored therapeutic trials currently incorporate these study end points.

The NCI sponsored this conference to promote the necessary development of economic evaluations in oncology and to initiate discussions on the importance, appropriateness, and complexity of the inclusion of such evaluations in future NCI trials. The format of the meeting was to use seven actual phase III therapeutic trials as examples of a research category in which an economic evaluation approach could be appropriately incorporated. For each trial, a clinical oncologist reviewed a particular phase III study, and a medical economist discussed the potential economic questions and study design in these trials. This protocol-based format was intended to provide investigators from the Clinical Cooperative Oncology Groups and NCI-sponsored clinical and comprehensive cancer centers with a general background and understanding of economic methodologies to help in the future design and conduct of clinical trials.

As anticipated, this meeting generated many more questions than answers. Perhaps primary among these questions are the following: Should cost analysis be a component of any therapeutic trial? When is it both reasonable and important to expend the resources to include an economic comparison in a phase III trial? To what extent will the economic question alter the trial design? For example, will such analyses increase the sample size or lengthen the necessary duration of follow-up? What are the societal implications of the economic outcome information? Can the study results be generalized beyond the specific trial? Does the treatment benefit justify the dollars and resources spent compared with alternative uses of the same funds?

These and other compelling issues will need to be considered in the design of future therapeutic trials. It is hoped that an open dialogue and the development of new alliances between cancer clinicians and economists will benefit patients as well as the entire research community. Integration of economics into the equation of resource allocation, however, must proceed with caution. Decisions involving choices between present and future health benefits or between individuals and patient groups will necessarily involve the most careful and objective deliberation. We hope that this meeting contributes to the oncologist's efforts to rigorously develop economics as a fundamental component of the evaluation of the effectiveness of cancer treatment.

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# Introduction to Clinical Economics: Assessment of Cancer Therapies

*Kevin A. Schulman, Henry A. Glick, K. Robin Yabroff,  
John M. Eisenberg\**

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**Recent changes in the health care environment have led to the assessment of the costs and benefits of cancer treatment as criteria for the evaluation of new cancer therapies. The methodological framework for these assessments is provided by the field of clinical economics, a discipline that combines the techniques from clinical medicine, economics, epidemiology, and biostatistics. This article reviews the concepts of clinical economics and issues related to economic analysis of new therapies. This type of information is increasingly important to patients, clinicians, and health policy decision makers to help assure patients' access to effective cancer therapies. [Monogr Natl Cancer Inst 19:1-9, 1995]**

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Traditionally, the evaluation of new medical technologies, such as different treatment modalities for patients with cancer, has focused on treatment efficacy, effectiveness, and safety. Recently, health care researchers from a variety of disciplines have developed new techniques for the evaluation of the economic impact of clinical care and medical technology. Clinicians, economists, epidemiologists, operations researchers, and others have all contributed to the field of "clinical economics"—an evolving discipline focused specifically on the study of different approaches to patient care and treatment and the influence of these approaches on the resources consumed in clinical medicine (1-19).

The growth of this field has proceeded rapidly as health policy makers have faced a continuing series of decisions about the funding of new clinical therapies in an era of increasingly constrained health care resources. Assessments of new therapies compare the new resources required for the treatment itself and the extent of substitution of the new resources for existing resources, if any, with the health outcomes resulting from the therapy. Thus, clinical economics includes not only an assessment of the cost of a new therapy, but also an assessment of its overall economic and clinical impact.

There is a growing appreciation for the need to apply the techniques of clinical economics to an assessment of patients with oncologic conditions. Cancer therapies may be resource intensive and of varying effectiveness. Clinical economics has been used extensively in the evaluation of screening programs for breast cancer (20-22), cervical cancer (23-26), prostate cancer (27), and colorectal cancer (28). More recently, clinical economics has been applied to the evaluation of new clinical strategies in the treatment of cancer patients (29-32).

Newer therapeutic modalities, such as bone marrow transplantation, can be very resource intensive, with the lowest median reported costs of \$40 000 (29). A retrospective analysis of the cost-effectiveness of high-dose chemotherapy with allogeneic bone marrow transplantation for a population of nonlymphocytic leukemia patients found a 33% increase in 5-year survival for patients receiving high-dose chemotherapy compared with those receiving usual care. Thus, the cost per year of life saved for this treatment was almost equivalent to that of usual care after 5 years, despite the higher initial costs associated with the high-dose chemotherapy (30).

Clinical evaluations of growth factors during autologous bone marrow transplantation have emphasized a reduction in resource consumption associated with the use of these new supportive treatments (29,31,32). An initial retrospective economic evaluation aggregated resource consumption measures to demonstrate that treatment with growth factors reduced overall treatment costs for patients undergoing high-dose chemotherapy and bone marrow transplantation (29).

In this article, we will review some of the health policy factors underlying the development of clinical economics and the terms and concepts of clinical economics. In addition, we will discuss the application of clinical economics to clinical research design.

## Development of Clinical Economics

Recent years have seen an increasing concern about the cost of medical care. This concern is leading internists, oncologists, health policy makers, health services researchers, and payors (private and public health insurers) to explore the economic consequences of current treatments for patients with cancer. These efforts result from an understanding that, in addition to differences in efficacy and safety, differences in efficiency (or the effectiveness of the treatment in actual clinical practice compared

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See "Note" section following "References."



with its cost) distinguish cancer therapies from each other and from other medical interventions.

Concerns about the cost of medical care are being expressed in nearly all developed nations. Canada is considering and Australia is implementing a set of national guidelines that would mandate the presentation of economic data at product registration for new pharmaceuticals to qualify for reimbursement through the national health insurance systems (33,34). Many European governments are considering similar reimbursement policies. The World Bank has recently used economic evaluation to assess health care priorities in developing countries (35).

In the United States, economic information is being used by the federal government in the evaluation of new medical technologies and new clinical services. The Agency for Health Care Policy and Research Reauthorization Act of 1992 establishes provisions for health care technology assessment to inform Medicare policy. In these efforts, the agency is instructed to consider the cost-effectiveness of technologies in assessments where cost information is available and reliable (36). A set of proposed regulations issued in 1989 by the Department of Health and Human Services would permit the Health Care Financing Administration to consider the cost-effectiveness of a service or technology in coverage or reimbursement decisions for Medicare patients (37). Economic analysis is increasingly being incorporated into the guideline development process to help shape the final treatment recommendations of the guideline panels.

The Clinton Administration presented the Health Security Act (HR 3600) concerning health care reform to the U.S. Congress and to the public (38) in the fall of 1993. Many of the details of health care reform proposals are now being debated at a more local level. At the present time, the use of clinical economics is being explored in benefit design, in program evaluation, and as a framework for assessment of medical technologies and interventions.

In the private sector in the United States, clinical economics research is increasingly being used by managed care organizations to make coverage decisions for new therapies. At the local level, hospital administrators and other providers of health care are seeking ways to deliver high-quality care within the constraints of limited budgets or reduced fee schedules. These decision makers increasingly are interested in guidance regarding the cost-effectiveness of new medical technologies such as cancer therapies. This guidance can be provided by clinical economic analyses.

The biotechnology revolution in medicine has added a series of challenging applications for clinical economics research. Clinical economics is being used increasingly to help understand the impact of new classes of therapies before they are brought to the marketplace. This framework is also being used to help determine appropriate clinical and economic outcomes for the clinical development program. This challenge is twofold: 1) to understand the potential impact of a therapy (e.g., should the evaluation of a new growth factor or cytokine be a short-term one, such as 30-day clinical efficacy, or a longer term end point that will capture the impact of these treatments on rehospitalization and relapse rates in the year following treatment) and 2) to understand the issues related to the transition

from efficacy to efficiency in clinical practice (39,40). These challenges span the clinical development spectrum. As we learn more about the potential impact and use of a new therapy, these issues can be re-addressed in an iterative process. Decision analytic models (41-44) can be used to address these economic and clinical issues surrounding new therapies at the beginning of the clinical development process and inform the research design process.

No single study can possibly provide all interested audiences with complete economic information on a new therapy. Thus, specific studies are undertaken to address economic concerns from specific perspectives, such as a study of a new chemotherapeutic agent from the perspective of a managed care organization. Studies may also be undertaken to assess the impact of therapy on specific cost categories, such as an assessment of the indirect costs of illness and its treatment in a disability assessment.

## Techniques of Clinical Economics

Economists emphasize that costs are more than just transactions of currency. Instead, they define cost as the consumption of a resource that could otherwise be used for another purpose. The value of the resource is that of its next best use, which no longer is possible once the resource has been used. This value is called the resource's "opportunity cost." For example, the time it takes to read this article is a cost for the reader, since it is time that cannot be used again. Good investments are made when the benefits of the investment (e.g., what you learn) are greater than or equal to the value of the opportunities you have foregone (e.g., what you would be doing if you were not reading this article).

In addition to the fact that not all costs involve a transaction of money, it is important to remember that, at least from the perspective of society as a whole, not all transactions of money should be considered a cost. For example, money transactions that do not represent the consumption of resources (e.g., Social Security payments, disability payments, or other retirement benefits) are not costs by this definition. They simply transfer the right to consume the resources represented by the money from one individual to another.

In considering economic analysis of medical care, there are three different dimensions of analysis, represented by the three axes of the cube in Fig. 1, with which readers should become familiar (1). Along the *x* axis, there are three different types of economic analysis: cost-identification, cost-effectiveness, and cost-benefit. Along the *y* axis, there are four points of view, or perspectives, that one may take in carrying out an analysis. One may take the point of view of society in assessing the costs and benefits of a new medical therapy. Alternatively, one may take the point of view of the patient, the payor, or the provider. Along the third axis, the *z* axis, are the types of costs and benefits that can be included in economic analyses of medical care. These costs and benefits, which will be defined below, include direct costs and benefits, indirect costs and benefits, and intangible costs and benefits.



# HEALTH ECONOMIC ANALYSIS

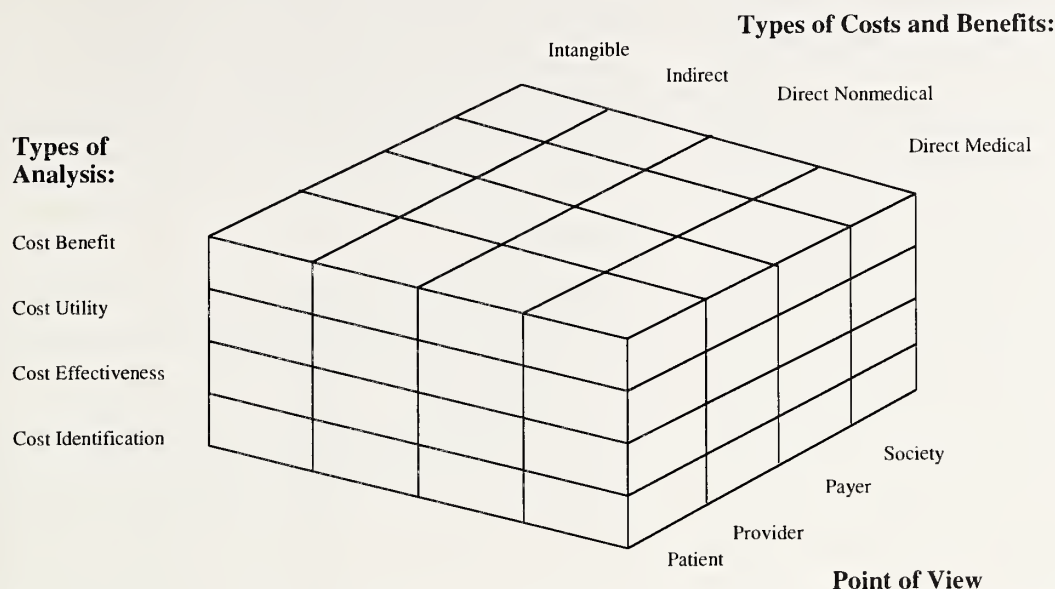


Fig. 1. Three dimensions of economic evaluation of clinical care. Adapted from Bombardier and Eisenberg (1).

## Types of Analysis

The three types of analysis performed in clinical economics are cost-benefit, cost-effectiveness, and cost-identification. Cost-benefit analysis of medical care compares the cost of a medical intervention with its benefit. Both costs and benefits are measured in the same (usually monetary) units (e.g., dollars). These measurements are used to determine either 1) the ratio of dollars spent to dollars saved or 2) the net savings (if benefits are greater than costs) or net cost. All else being equal, an investment should be undertaken when its benefits exceed its costs.

Costs and benefits are considered to be either positive or negative. A cost can be incurred or avoided; a benefit can be gained or lost. Thus, the cost-benefit ratio is open to manipulation. For example, by reclassifying a cost that is incurred as a lost benefit, one can move the term from the numerator (where it would be considered a cost) to the denominator (where it would be considered a negative benefit). The net savings calculation, where cost and benefits are summed together, cannot be manipulated in this way and thus is generally preferred.

The methods of cost-benefit analysis may be applied to evaluate the total cost and total benefits of the interventions that are being compared by analyzing their cost-benefit ratios or their net benefits. Furthermore, the additional or "incremental" cost of an intervention (e.g., the difference in cost between a new therapy and conventional medical care) may be compared with its additional or "incremental" benefit. Incremental analysis is generally preferred to comparisons of the totals because it allows the analyst to focus on the differences between any two treatment modalities.

One of the potential difficulties of cost-benefit analysis is that it requires researchers assessing a medical intervention to express both its cost and outcome in the same units. Thus, money

values must be associated with years of life lost and morbidity due to disease and with years of life gained and morbidity avoided as a result of intervention. Expressing costs in this way is obviously difficult in health care analyses. Outcomes (treatment benefits) may be difficult to measure in units of currency. Translating disease and treatment outcomes into monetary measures may be more difficult than translating them into clinical outcome measures, such as years of life saved or years of life saved adjusted for quality.

Cost-effectiveness analysis provides an approach to the dilemma of assessing the monetary value of health outcomes as part of the evaluation. While cost is generally still calculated solely in terms of dollars spent, effectiveness is determined independently and may be measured solely in clinical terms, using any meaningful clinical unit. For example, one might measure clinical outcomes in terms of number of lives saved or number of toxic effects prevented. Alternatively, health outcomes can be reported in terms of a change in an intermediate clinical outcome, such as cost per case with a complete response to treatment. Results of cost-effectiveness analysis generally are reported as a ratio of costs to clinical benefits, with costs measured in monetary terms but with benefits measured in the units of the relevant outcome measure (e.g., dollars per year of life saved).

When several outcomes result from a medical intervention (e.g., the prevention of both death and disability), cost-effectiveness analysis may consider these two outcomes together only if a common measure of outcome can be developed. Frequently, analysts combine different categories of clinical outcomes according to their desirability and assign a weighted utility, or value, to the overall treatment outcome (3,4). A utility weight is a measure of the patients' preferences for their health state or for the outcome of an intervention. The comparison of costs and utilities sometimes is referred to as cost-utility analysis.

As with cost-benefit analysis, cost-effectiveness analysis can compare a treatment's total costs and total effectiveness, or it can assess only the treatment's incremental costs and incremental effectiveness. In the total cost and effectiveness method, the cost-effectiveness ratio of each intervention is calculated, and the two ratios are compared (e.g., the cost per complete response using each intervention). In the incremental cost and effectiveness method, the additional (incremental) cost of the innovation is calculated, as is the additional (incremental) effectiveness, and the analyst can calculate the additional effect (e.g., number of complete responses) per additional treatment dollar spent.

Programs that are cost saving with improved or equivalent treatment outcomes are said to be "dominant" and should always be adopted. Programs that cost more and are more effective should be adopted if both their cost-effectiveness and incremental cost-effectiveness ratios fall within an acceptable range, and the budget for the program is acceptable. Programs that cost more and have worse clinical outcomes are said to be dominated and should never be adopted. Programs that cost less and have reduced clinical outcomes may be adopted depending on the magnitude of the cost and outcome changes.

As with the translation of clinical outcomes into monetary measures, there also are difficulties associated with combining different outcomes into a common measure in cost-effectiveness analysis. It is generally considered more difficult, however, to translate all health benefits into monetary units for the purpose of cost-benefit analysis than to combine measures of clinical outcomes. Thus, cost-effectiveness analysis is used more frequently than cost-benefit analysis in the literature on medical care.

An even less complex approach than cost-benefit or cost-effectiveness analysis would be simply to enumerate the costs involved in medical care and to ignore the outcomes that result from that care. This approach is known as "cost-identification" analysis. By performing cost-identification analysis, the researcher can determine alternative ways of providing a service. This analysis might be expressed in terms of the cost per unit of the service provided. For example, a cost-identification study might measure the cost of a course of specific regimen of chemotherapy or the cost of an outpatient transfusion program, but it would not calculate the clinical outcomes (that would be a cost-effectiveness analysis) or the value of the outcomes in units of currency (that would be a cost-benefit analysis). Cost-identification studies, which include the comparison among different treatments based on their costs alone, are appropriate only if treatment outcomes or benefits are equivalent for the therapies being evaluated.

Most cost-benefit and cost-effectiveness studies require large amounts of data that may vary in their reliability, in their validity, or in their impact on the overall results of the study. This is especially the case where models are developed for the economic analysis using secondary data sources, where data collection is performed retrospectively, or where critical data elements are unmeasured or unknown. Sensitivity analysis is a set of procedures in which the results of a study are recalculated using alternate values for some of the study's variables in order to test the sensitivity of the conclusions to these altered variable specifications. Such an analysis can yield several important

results, including demonstrating the independence or dependence of a result on particular assumptions; establishing the minimum or maximum values of a variable that would be required to affect a recommendation to adopt or reject a program; and identifying clinical or economic uncertainties that require additional research. In general, sensitivity analyses are performed on variables that have an unknown value in order to estimate the impact of the uncertainty on the study's conclusions.

## Types of Cost

Another dimension of economic analysis of clinical practice illustrated by Fig. 1 is the evaluation of costs of a therapy. Economists consider three different types of costs—direct, indirect, and intangible.

The direct medical costs of care usually are associated with monetary transactions and represent costs that are incurred in providing care. Examples of direct medical costs include payments for the purchase of a pharmaceutical product, paying a physician's fee, paying the salary of an allied health professional, or purchasing a diagnostic test. Since the charge for medical care may not accurately reflect the resources consumed, accounting or statistical techniques may be needed to determine these direct costs (7,45-48).

Monetary transactions undertaken as a result of illness or health care to detect, prevent, or treat disease are not limited to direct medical costs alone. There is another type of cost that often is overlooked: direct nonmedical costs. These costs are incurred because of illness or the need to seek medical care. They include the cost of transportation to the hospital or physician's office, the cost of special clothing needed because of the illness, the cost of hotel stays for receiving medical treatment at a distant medical facility, and the cost of special housing (e.g., the cost of modification of a home to accommodate an ill individual). These costs, which are generally paid out of pocket by patients and their families, are just as much direct medical costs as are expenses that are more usually covered by third-party insurance plans.

Direct medical costs can be further classified to help understand the potential impact of a therapy in terms of the ability to change patterns of resource consumption by patients. If these costs increase with increasing volume of activity, they are described as variable costs. However, if the same costs are incurred regardless of the volume of activity, they are described as fixed costs. For example, the cost of paper used in an electrocardiogram machine is a variable cost, since a strip of paper is used for every tracing. However, the cost of the machine itself is a fixed cost, since it must be purchased whether one tracing is needed or many are performed. Of course, fixed costs are fixed only within certain bounds. A very large increase in activity will require the purchase of another piece of equipment. Even the fixed cost of a hospital's building is only fixed within certain limits of activity and a certain time frame. If enough increase in activity occurs, a new building might be needed. Alternatively, if patient care is transferred from an inpatient to an outpatient setting, a part of the building may be closed, and the staff size decreased. Still, for the purposes of most decisions in clinical practice, costs can be considered to be fixed or variable.



Indirect costs, in contrast to direct costs, do not stem from transactions for goods or services. Instead, they represent the cost of morbidity (e.g., time lost from work) or mortality (e.g., premature death leading to removal from the work force). They are costs because they represent the loss of opportunities to use a valuable resource, a life, in alternative ways. Various techniques are used to estimate these indirect costs of illness or health care (49-53). Sometimes, as with patients infected with the human immunodeficiency virus (54), the indirect costs of an illness are substantially greater than the direct costs of the illness.

Intangible costs are those of pain, suffering, and grief. These costs result from the medical illness itself and from the medical care services used to treat the illness. They are difficult to measure as part of a clinical economics study, though they are clearly considered by clinicians and patients in deciding among alternative treatments. Investigators are developing ways to measure intangible costs, such as Willingness-to-Pay analysis in which patients are asked to place monetary values on intangible costs (3,4). At present, however, these costs are often omitted in clinical economics research.

## Perspective of Analysis

The third axis in Fig. 1 is that of the perspective of an economic analysis of medical care. Costs and benefits can be calculated with respect to the point of view of society, the patient, the payor, and/or the provider. A study's perspective determines how costs and benefits are measured, and the economist's strict definition of costs (the consumption of a resource that could otherwise be used for another purpose) no longer may be appropriate when perspectives different from those of society as a whole are used. The economic impact of an intervention will be reported differently, depending on the perspective taken.

For example, a hospital's cost of providing a service may be less than its charge. From the hospital's perspective then, the charge could be an overstatement of the resources consumed for some services. However, if the patient has to pay the full charge, it is an accurate reflection of the cost of the service to the patient. Alternatively, if the hospital decreases its costs by discharging patients early, the hospital's costs may decrease, but patients' costs may increase because of the need for increased outpatient expenses that are not covered by their health insurance plan.

Similarly, the cost to society is the opportunity cost, the value of the opportunities foregone because of the resource having been consumed. Society's perspective is usually taken by measuring the consumption of real resources, including the loss of potentially productive human lives. As already noted, this cost does not count transfer payments such as Social Security benefits. (From the point of view of the Social Security Administration, however, these payments would be a cost, as the perspective of the Social Security Administration is not the perspective of society.)

There is a growing recognition that cancer affects both patients and families and that the family or caregivers may have their own perspectives on the patient's illness and treatment.

Because the costs of medical care may not be borne solely by the same parties who stand to benefit from it, economic analysis of medical care often raises vexing ethical problems related to equity, the distribution of resources, and responsibility for the health of society's members (55,56).

In summary, economic analysis of medical technology or medical care evaluates a medical service by comparing its dollar cost with its dollar benefit (cost-benefit), by measuring its dollar cost in relation to its outcomes (cost-effectiveness), or simply by tabulating the costs involved (cost-identification). Direct costs are generated as services are provided. In addition, indirect costs should be considered, especially in determining the benefit of a service that decreases morbidity or mortality. Finally, the point of view, or perspective, of the study determines the costs and benefits that will be quantified in the analysis, and sensitivity analyses test the effects of changes in variable specifications for estimated measures on the results of the study.

## Economic Evaluation of New Clinical Therapies

New clinical therapies are developed in a series of well-defined stages. After a treatment is identified and thought to be clinically useful, four distinct sets of evaluations—referred to as phase I through IV studies—may be conducted. In phase I studies, the new compound is first introduced into humans, principally for the evaluation of safety and dosage. In phase II studies, the drug is introduced into a patient population with the disease of interest, again principally for the evaluation of safety and dosing. In phase III studies, randomized trials are done in which the safety and efficacy of new therapies are evaluated and compared either with those of a placebo or those of a therapy that the new treatment potentially might replace. In addition to these three types of studies, therapies can be evaluated after adoption in what are often referred to as phase IV studies. This development process allows for timely collection of data that can be used to evaluate the costs and effects of treatments early in their clinical development, with an opportunity for further data collection and evaluation once the therapy has been more widely adopted.

Clinical economics needs to be integrated throughout this development process, with goals that parallel those of each clinical development stage. Phase I and phase II studies are used to develop pilot economic data, such as estimates of the mean and variance estimates for costs, quality of life, and utilities for patients with a specific clinical syndrome. These studies are also used to perform pilot tests of data-collection tools, including economic case report forms that prospectively capture resources used by patients who will be entered into the phase III and phase IV clinical trials (Figs. 2 and 3). From these data, sample size for clinical economic studies can be calculated. Without these data, the minimum detectable differences between trial arms for a fixed sample size and power can be assessed using Table 1 (57,58).

One of the fastest growing areas in the economic assessment of new therapies is the inclusion of economic analyses as part of phase III clinical trials. Phase III studies can include economic assessments of new therapies as a primary or secondary end point (i.e., an assessment of changes in the use of specific resource categories resulting from treatment, such as changes in

<b>HOSPITAL DISCHARGE FORM</b>		Patient No. _____
Principal Investigator _____	Study Hospital _____	Date of Admission __/__/__ Date of Discharge __/__/__
Source of Admission <input type="checkbox"/> Emergency room <input type="checkbox"/> Transfer (from _____) <input type="checkbox"/> Elective	Discharge Diagnosis 1. _____ 2. _____	
Unit Type		Number of Days
Intensive Care Unit		
Intensive Care Unit with Mechanical Ventilator		
Bone Marrow Transplant Unit		
Step-Down\Intermediate Care Unit		
General Medical or Surgical Floor		
Pharmacologic Therapy		Total Dose
<input type="checkbox"/> Cytosan (cyclophosphamide) _____		
<input type="checkbox"/> Adriamycin (doxorubicin hydrochloride) _____		
Other _____		
Types of Procedures		Date
Place Hickman Catheter		
Bone Marrow Biopsy		
Other _____		
Diagnostic Tests		Number of Tests
MRI		
CT Scan		
Bone Scan		

Fig. 2. Inpatient resource assessment. This is a sample case report form for prospective assessment of inpatient resource consumption in a pharmacoeconomic study.

the use of blood products, changes in the length of hospital stay, or changes in hospitalization rates that result from side effects of outpatient cancer treatment). Lastly, there is a wide variety of phase IV economic studies that can be performed. These studies

include efficiency trials and surveillance studies. In efficiency trials, comparisons between treatments are made in more realistic patient care settings than those of phase III studies, with less restrictive protocols. These phase IV studies may include assess-



OUTPATIENT VISIT RECORD				Patient No. _____	
Name of Physician and Location of Visit (eg., Emergency Room, Outpatient Clinic, Day Surgery, Home, Office)				Duration (in minutes)	
				date __\__	date __\__
1.					
2.					
3.					
Name of Nurse Clinician and Location of Visit (eg., Emergency Room, Outpatient Clinic, Day Surgery, Home, Office)				date __\__	date __\__
				date __\__	date __\__
1.					
2.					
Type of Procedure					Date
1. Bone Marrow Biopsy					
2. Chemotherapy Infusion					
3. Transfusion					
Diagnostic Tests					Number of Tests
MRI					
CT Scan					
Bone Scan					
Other					
Other Therapy (medications, etc.)					Date
1. MSO <sub>4</sub> Pump					
2.					
3.					

**Fig. 3.** Outpatient resource assessment. This is a sample case report form for prospective assessment of outpatient resource consumption in a pharmacoeconomic study.

ments of the new therapy compared with "usual care" or compared with other specific treatments. These studies may also examine the effect of therapy in less specialized settings than National Cancer Institute cancer centers. In phase IV surveil-

lance studies, observational data may be used to evaluate costs, effectiveness, and adverse experiences related to the therapy. Again, the economic analysis can serve as a primary or secondary end point of the study.

Table 1. Study differences detectable given a fixed sample size\*

Standard deviation, length of stay/\$	Detectable difference $R^2$ for covariables			
	0	.1	.2	.3
5	2	2	1	1
10	3	3	3	3
20	6	6	6	5
30	10	9	9	8
40	13	12	12	11
50	16	15	14	14
100	32	31	29	27
500	162	153	145	135
1000	324	307	289	271
2500	809	767	723	677
5000	1618	1535	1447	1354

\*n = 150 group;  $\alpha/2 = 0.05$ ;  $\beta = 0.2$ ; power = 0.8. Values represent minimum detectable differences between trial arms given the standard deviation reported for the row in the table and a fixed sample size for each arm of the trial.  $R^2$  is the measure of the variance explained by the base-line values of the independent variables excluding the study variable (i.e., the variable representing randomization) (57,58).

Developing economic data as end points in a clinical trial requires careful consideration and planning. While there has recently been an increase in the number of clinical trials that are collecting these economic data, the challenge remains to ensure that clinical economics end points are considered sufficiently early in the clinical development process to inform design of the clinical trial. Economic analysis requires the establishment of a set of economic end points for study (e.g., direct, indirect, or intangible cost to patients and caregivers and quality-of-life or preference measures for patients and caregivers), review of the clinical protocol to ensure that there are no economic biases in the design of the clinical trial (e.g., hospital discharge criteria that vary across treatment arm), and the development of the economic protocol. Ideally, the economic study will be integrated into the clinical protocol, and the economic data will be collected as part of a unified case report form for both clinical and economic variables.

## Summary

The emergence of cost as a criterion for the evaluation of new technologies requires the continued development and application of research methods to guide decision makers. Patients and physicians acting on their behalf are principally concerned about treatment effectiveness and safety. However, as patients, payors, and society become more concerned about the cost of medical care, the clinical contribution of new therapeutic modalities for the treatment of cancer patients will be weighed against their costs and compared with the next best alternative.

A full economic analysis of a cancer therapy should go beyond the identification of cost. Only if the safety and effectiveness of two treatments are equivalent will cost alone determine the choice of therapy. Cost-effectiveness analysis requires that cost be weighed against effectiveness and that when two or more alternatives are being compared, the additional cost per additional unit of effectiveness be measured. Beyond these considerations of cost-identification and cost-effectiveness, a full

economic analysis will also assess the net value, or utility, of the therapy's clinical contribution.

As oncologists and other physicians are asked simultaneously to represent their patients' interests and to deliver clinical services with parsimony, they increasingly will need to turn for assistance to collaborative efforts of epidemiologists and economists in the assessment of new therapeutic strategies. Through a merger of epidemiology and economics (59), better information can be provided to clinical decision makers, and limited resources can be used most effectively for the health of the public.

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## Note

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# Special Issues That Arise in Applying Techniques of Economic Analysis to Evaluation of Cancer Therapies

Jane C. Weeks\*

The papers presented at this conference and reprinted in this monograph provide an opportunity to begin the process of establishing a shared language, set of goals, and "methods tool chest" for clinical researchers and economists to use in approaching the integration of economic analysis into cancer clinical trials. The first step in this process should be to recognize that there are several special issues that arise in applying the techniques of economic analysis to the evaluation of cancer therapies. These issues include the following: 1) The clinical course of cancer is complex, 2) clinical research and clinical trials are in the mainstream of cancer care, 3) cancer therapy is multidisciplinary, and 4) "best supportive care" is a rarely studied alternative. [Monogr Natl Cancer Inst 19:11-12, 1995]

The increasing application of proven techniques of economic analysis to cancer clinical trials is likely to yield valuable insights into the costs and benefits of new and established therapies. The papers presented at this conference and published in this monograph provide an opportunity to begin the process of establishing a shared language, set of goals, and "methods tool chest" for clinical researchers and economists to use in approaching the integration of economic analysis into clinical trials.

As one of a small but growing number of oncologists who have spent some time in the company of economic analysts, I have come to realize that oncologists are not the only people who need acculturation if this process is to be a success. Economists must also share with oncologists an understanding of the following four special issues raised by clinical research and clinical care in cancer therapy that need to be considered in designing and interpreting economic analyses in our field.

1) *The clinical course of cancer is complex.* To date, economic analyses have been especially effective in assessing the costs and outcomes of interventions to prevent and diagnose disease and to treat chronic conditions such as hypertension or hypercholesterolemia. In general, these analyses deal with clinical outcomes that are easily "countable," such as stroke or blindness, and chronic health states that are characterized by relatively stable quality of life over time. In contrast, the clinical course of cancer is often complex, with fluctuating levels of quality of life reflecting interactions between the morbidity of the disease and the toxicity of the therapy. Trade-offs between early disease control and late sequelae, both malignant and nonmalignant, may also characterize the clinical course of cancer patients, par-

ticularly children with cancer. The assessment of the value of resources spent in an effort to improve these complex outcomes may create new challenges for economic analysis.

First, because the outcomes for so many cancers are poor, the disease is particularly dreaded and stigmatizing. Therefore, economic analyses of cancer therapy may be especially prone to political attack on the grounds that we should not endorse, implicitly or explicitly, "rationing" of cancer therapy based on economic considerations. Moreover, practitioners may be reluctant to enroll patients in clinical trials that include an economic component because of concern that the results of that analysis may be used to restrict their ability to provide compassionate care to their patients in the future. In particular, they may worry that economic arguments will be used to limit their freedom to offer desperately ill patients treatments that will palliate without prolonging life or will provide a small but not nonexistent chance of long-term survival.

Even more important than the political challenges may be the methodological issues that must be resolved if we are to integrate economic analysis into trials of cancer therapy. For example, there is a real need to develop better methods for incorporating not only the survival benefit but also the palliative effects of cancer therapy into decisions about whether the benefits of new and established therapies justify their costs.

Finally, the nature of the clinical outcomes in cancer will require us to address a number of practical issues if we are to successfully integrate economic analyses into clinical trials. In particular, the incorporation of economic analyses may require changes in the way we currently design and conduct clinical trials. For example, the primary goal of a randomized clinical trial is to identify which strategy results in better disease-free and overall survival. But if the trial is also to be the source of an estimate of effectiveness for a cost-effectiveness ratio, follow-up may need to be prolonged in order to estimate with some precision the difference in the areas under the survival curves and the influence of late sequelae on costs.

2) *Clinical research and clinical trials are in the mainstream of cancer care.* While the strong commitment to clinical research in the oncologic community sets the stage for assessment

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of a broader array of outcomes, it also raises issues that bear on the acceptance and generalizability of study findings. Oncologists are unusually sophisticated in their understanding of clinical research methods and have been trained to demand proof of statistical significance before they accept claims of clinical efficacy. As a result, oncologists may look askance at the conclusions of decision-analytic models or other results that are not accompanied by a *P* value.

Acceptance of the findings of studies of economic outcomes in clinical trials will be enhanced if we all take extra care to present our methods clearly in published reports of the studies. In addition, educational efforts, such as reviews in oncology journals and sessions at national oncology meetings that reach a broad audience of clinical researchers and practitioners in the field, may be useful in overcoming some resistance to these unfamiliar methods.

The prominent role played by specialized cancer centers creates the potential for a distorted assessment of the costs of care, since data collected in these centers may be atypical with respect to costs, patient characteristics, and clinical practice patterns. A reliance on resource-use data rather than on charges in estimating costs of alternative methods will help minimize these distortions. The multipliers used to transform resource-use estimates into costs can then be chosen to reflect the experience of centers where the majority of cancer patients receive their care rather than the idiosyncratic reimbursement structures many of the comprehensive cancer centers have had the privilege to enjoy.

Finally, there is understandable concern among oncologists that undue emphasis on economic considerations may undermine clinical research by discouraging investment in innovative therapies. It will be especially important for those of us who work on economic analyses in cancer to take care in reporting our results to acknowledge the potential effect of a learning curve on costs. But perhaps the best reassurance that can be offered to skeptics in the clinical research community is evidence that the National Cancer Institute recognizes that, if we are to obtain data on economic as well as conventional biologic outcomes, it will require enhanced, not diminished, support for clinical trials.

3) *Cancer therapy is multidisciplinary.* Alternative treatment strategies for a given disease often involve a complex mix of inputs. Calculation of the incremental costs of one treatment over another may necessitate comparisons of inpatient therapy with

outpatient therapy or chemotherapy with radiotherapy, for example. Such comparisons will be more sensitive to decisions about the use of charges as opposed to costs or to the idiosyncratic structure of an institution's fee schedule than would comparisons involving a single treatment modality. In addition, they will require collection of cost and resource-use data from a number of sources, including outpatient clinics and various home care programs; these data are much more difficult to obtain and to track over time than inpatient costs.

One of the challenges of performing a cost-effectiveness analysis in which complex alternative treatment strategies are compared is to figure out where the major differences in costs lie and to concentrate data-collection efforts on those areas. While the nature of the type of treatments offered in oncology creates these methodologic challenges for economic analysis, it also provides the opportunity to develop an effective solution. The notion of phased trials, in which the evaluation of a new therapy occurs in an ordered series of steps, is second nature to clinical researchers in oncology. This structure may provide a useful model for the development of a systematic approach to collection of complex economic data as well.

4) *"Best supportive care" is a rarely studied alternative.* From a policy perspective, the most compelling questions in oncology often involve the comparison of aggressive treatment regimens with alternatives that emphasize supportive care. In the United States, researchers and patients have been reluctant to participate in such trials. In general, the choice of the optimal alternative therapy for the purposes of economic analysis may not be the same as the choice that would be dictated by political, biological, or clinical considerations.

For example, the most efficient means of answering biological questions in the field may be to conduct phase III trials in which the arms differ in the dose or timing of administration of a relatively new regimen. In contrast, the most important question for policy makers, and consequently economists, may be whether the additional benefits of either version of this regimen over "conventional" therapy are sufficient to justify its incremental cost compared with the less expensive alternative.

In the future, collection of the most interesting data for economic analyses may require that health-services researchers form an alliance with oncologists to identify and design priority trials. This process is more likely to succeed if this meeting proves to be the beginning of an ongoing dialogue rather than a single, if well-intentioned, conversation.



# Whole Abdominal Radiotherapy Versus Combination Chemotherapy With Doxorubicin and Cisplatin in Advanced Endometrial Carcinoma (Phase III): Gynecologic Oncology Group Study No. 122

*Marcus E. Randall, Nick M. Spirtos, Phil Dvoretzky\**

Although localized endometrial cancer is effectively treated with surgery and radiation therapy, the treatment of advanced disease remains problematic. With increasing utilization of primary surgical staging and therapy, the early identification of patients with tumor spread beyond the uterus is becoming routine. The impact of adjuvant radiotherapy and/or chemotherapy in these patients remains to be demonstrated. In several institutions, whole abdominal radiation therapy has been used with some success as adjuvant treatment in selected patients with advanced disease. The Gynecologic Oncology Group (GOG) has completed a phase II trial of the whole abdominal radiotherapy in this patient population. Although data analysis is not complete, the regimen employed appears to be tolerable and shows some evidence of efficacy. In previous GOG trials, cisplatin and doxorubicin have shown single-agent activity in patients with measurable, advanced endometrial cancer. Subsequently, the response rate with the combination of cisplatin and doxorubicin was found to be superior to that with doxorubicin alone. Because approximately 30%-50% of patients with extrauterine disease have systemic failure, the evaluation of combination chemotherapy with doxorubicin and cisplatin in the adjuvant setting seemed warranted. The current ongoing prospective, randomized trial (GOG No. 122) compares the survival and the progression-free interval and treatment failure patterns in patients with endometrial carcinoma of stage III or IV with up to 2 cm of residual disease when treated with either whole abdominal radiotherapy or a combination of doxorubicin and cisplatin. The incidence and type of acute and late adverse events observed with the two treatment regimens were determined and compared. [Monogr Natl Cancer Inst 19:13-15, 1995]

With some 34 000 new cases diagnosed annually in the United States, endometrial carcinoma is the most common gynecologic malignancy. If diagnosed before disease progression and metastasis, localized endometrial cancer may be effectively treated by surgery and radiation therapy. Treatment of advanced disease, however, remains problematic. The American Cancer Society estimates that 5900 women will have died of en-

dometrial cancer in 1994 (1), with the vast majority of deaths occurring in patients with advanced disease.

Because of the inherent inaccuracies associated with clinical staging, the International Federation of Gynecologists and Obstetricians (FIGO) revised the staging system for endometrial carcinoma in 1988 (2). Initial surgicopathologic staging, including retroperitoneal lymph node sampling, is currently considered appropriate for most patients.

Stage IIIA is now identified by the presence of positive serosa, adnexae, or cytology; stage IIIB, by vaginal metastasis; stage IIIC, by positive pelvic or periaortic lymph nodes; stage IVA, by urinary bladder or bowel mucosal metastasis; and stage IVB, by distant intra-abdominal or inguinal lymph node metastasis. Commonly recognized prognostic factors are surgical stage, histologic grade, the presence and depth of myometrial invasion, vascular space invasion, cytologic washings, and extrauterine and stromal spread. Disease-free survival for patients with stage III disease is estimated at 43% (3).

With the increasing use of primary surgical staging and therapy, the early identification of patients with tumor spread beyond the uterus is becoming routine. Adjuvant radiotherapy or adjuvant chemotherapy is employed for the treatment of patients with advanced endometrial carcinoma based on the presence of recognized risk factors. The impact of adjuvant radiotherapy (pelvic or abdominal) and/or adjuvant chemotherapy in these patients remains to be clearly demonstrated.

## Adjuvant Radiotherapy

Various investigators have observed that patients with extrauterine spread limited to the peritoneal fluid and/or adnexa (stage IIIA) have favorable outcomes compared with patients with nodal or other intra-abdominal metastases [reviewed in

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(4)]. These data support the division of endometrial carcinoma into "favorable" and "unfavorable" categories. This distinction is potentially important in terms of adjuvant radiotherapy, although histologic grade, age, and amount of residual disease (i.e.,  $\geq 2$  cm) after debulking are obvious mitigating factors. Predominantly, pelvic radiotherapy has been used as adjuvant therapy for these stage IIIA patients; of note, however, is the fact that the best reported survival rates (88%-100%, with median follow-up of 3 years) have been in studies that used whole abdominal radiotherapy as adjuvant therapy for isolated adnexal involvement.

The increased use of surgical staging with pathologic assessment of lymph nodes and other possible sites of extrauterine involvement has underscored the high correlation of positive cytology with other extrauterine spread, although wide differences in the percentages of patients having both positive cytology and extrauterine spread have been found in several studies, leaving many unanswered questions. Is the recurrence rate reduced or the pattern of failure altered by adjuvant treatment? If so, what treatment is the most effective? What risks are associated with the various adjuvant treatments?

Although the possibility exists that adjuvant radiotherapy can reduce recurrence risk in patients with isolated positive cytology, it is presently impossible to determine on the basis of available data whether that treatment should be local, regional, or systemic.

Many patients with positive cytology have other extrauterine involvement (e.g., nodal). In these patients, prognosis appears to be more significantly associated with risk factors other than positive cytology. For such patients, the treatment approach may depend on these noncytologic factors, although the selection of adjuvant radiotherapy (e.g., whole abdominal radiation versus pelvic radiotherapy in patients with positive pelvic lymph nodes) will be influenced to some degree by the status of peritoneal cytology.

The site of metastatic involvement in advanced endometrial cancer has both staging and prognostic importance. Furthermore, the number of intra-abdominal metastatic sites is strongly prognostic. Stage III patients treated with initial surgery and postoperative radiotherapy and having two or more involved sites had a 5-year actuarial abdominal recurrence rate of 31%, significantly higher than that of patients with single-site metastases of any grade (5). Whole abdominal radiotherapy could have a significant impact on survival in these patients if the intra-abdominal recurrence rate is understated and if improved control of abdominal disease translates into a decreased rate of distant spread (6).

Adjuvant treatment for patients with pelvic adenopathy as the solitary site of extrauterine involvement (FIGO stage IIIC) remains pelvic radiotherapy; however, for patients with multiple involved nodes, whole abdominal radiotherapy and extended field radiotherapy may be more appropriate. Satisfactory adjuvant treatment for patients with pelvic adenopathy in addition to other extrauterine spread remains to be identified. Some investigators (7,8) have concluded that adjuvant radiotherapy can be curative in approximately 40% of patients with para-aortic metastases; however, whether the treatment of choice is whole abdominal radiotherapy or extended field radiotherapy has not

been resolved. Furthermore, the rate of abdominal recurrence among patients presenting with para-aortic lymph node metastases is unclear, and clinical results are conflicting.

In several institutions, whole abdominal radiotherapy has been used with some success as adjuvant treatment in selected patients with advanced disease. The Gynecologic Oncology Group (GOG) has completed a phase II trial of whole abdominal radiation in this patient population. Although data analysis is incomplete, it appears that the whole abdominal radiation regimen is tolerable, with some evidence of efficacy (4).

## Adjuvant Chemotherapy

In previous GOG trials, doxorubicin and cisplatin have shown single-agent activity in patients with measurable, advanced endometrial carcinoma (9,10). Subsequently, the response rate with the combination of doxorubicin and cisplatin (AP) has been found to be superior to that with doxorubicin alone (11). Despite the excellent response rate, the time to disease progression and median survival for most patients have generally ranged from 4 to 10 months (12). Because approximately 30%-50% of patients with extrauterine disease demonstrate systemic failure, the evaluation of AP in the adjuvant setting seems warranted.

## Objectives of GOG Study No. 122

The objective of GOG Study No. 122 is to compare treatment outcomes (i.e., survival, progression-free interval, or treatment failure) following treatment either with whole abdominal radiotherapy or with AP in patients with endometrial carcinoma of stage III or IV having residual disease of 2 cm or less. In addition, the incidence and types of acute and late adverse events associated with the two treatment arms are compared.

For this study, survival is defined as the observed length of life from study entry to death or, for living patients, the date of last contact, regardless of whether or not the contact is on a subsequent protocol. The progression-free interval is defined as the date from study entry to the date of reappearance or increasing parameters of disease or as the date of last contact.

## Study Population

This study will attempt to enroll at least 240 patients with advanced endometrial carcinoma of any histology, including clear-cell and serous papillary carcinoma. Patients may have positive adnexa, tumor invading the serosa, positive pelvic and/or para-aortic lymph nodes, involvement of bowel mucosa, intra-abdominal metastases, positive pelvic washings, or vaginal involvement within the radiation port. All patients in the study population will have undergone total abdominal hysterectomy and bilateral salpingo-oophorectomy, with tumors maximally debulked to 2 cm or less. The disease in all patients with positive para-aortic nodes will be further staged by scalene node biopsy and chest computed tomography scan, both of which must be negative. (Patients with positive results are referred to other GOG protocols.) Patients may have received prior progestational therapy but not previous radiotherapy or chemotherapy.



## Exclusion Criteria

Exclusion criteria include the following: recurrent disease; residual tumor exceeding 2 cm in maximum dimension (any single site) following debulking; metastases (parenchymal liver or lung); positive inguinal or scalene lymph nodes; previous pelvic or abdominal radiation therapy or chemotherapy; inadequate hematologic, renal, or hepatic function (i.e., white blood cell count  $<3000/\text{mm}^3$ , platelet count  $<100\,000/\text{mm}^3$ , granulocyte count  $<1500/\text{mm}^3$ , creatinine level  $>2.0\text{ mg}/100\text{ mL}$ , bilirubin level  $>1.5$  times normal, and aspartate aminotransferase level  $>3$  times normal); GOG performance grade 4 (Karnofsky scale of 10 and 20, with the patient completely disabled and not capable of any self-care); and previous or concomitant malignancy other than skin cancer (excluding melanoma).

## Treatment Arms

The treatment arms in this study are as follows:

1) Whole abdominal irradiation with opposed fields; total dose of 3000 cGy in 20 fractions of 150 cGy, with daily fraction decreasable to 125 cGy per day for patients having leukopenia or gastrointestinal symptoms. All fields are treated with each fraction once daily for 5 days per week. Patients with positive pelvic and/or para-aortic lymph nodes receive boosts to both areas; other patients receive boosts to the true pelvis only. (A boost consists of an isocenter dose of 1500 cGy per eight fractions.) The radiation field in whole abdominal irradiation extends from the dome of the diaphragm to the pelvic floor, with lateral borders set approximately 1.0-1.5 cm beyond the lateral peritoneal margin. Liver shielding is eliminated to ensure adequate treatment for the underside of the diaphragm. Shielding of the left side of the heart and posterior kidney blocks is advisable throughout the whole abdominal radiation therapy.

2) Doxorubicin at  $60\text{ mg}/\text{m}^2$  intravenously plus cisplatin at  $50\text{ mg}/\text{m}^2$  intravenously every 21 days for eight courses (maximum total doxorubicin dose of  $480\text{ mg}/\text{m}^2$ ).

## Study Duration

The GOG estimates a 4-year patient accrual (60 patients annually) and a follow-up of 3-4 years, for a total study duration of 7-8 years.

## Patient Follow-up

Patients will be seen for complete re-evaluations at the conclusion of the treatment course. They will be followed with no further therapy until progression of disease is documented.

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# Economic Considerations in Comparing Whole Abdominal Radiotherapy With Combination Doxorubicin–Cisplatin Chemotherapy in Advanced Endometrial Carcinoma: How Much Economic Data Should Be Collected?

Jane C. Weeks\*

The key features of this study from the perspective of designing an economic analysis are that the resources consumed and the expected toxic effects are likely to be quite different in the two study arms, median survival will be measured in years, and the initial treatment assignment may affect the clinical course and resource consumption of the terminal phases of illness. Collecting complete data on all the costs associated with treatment, short-term toxic effects, long-term toxic effects, and treatment of recurrent disease as well as tracking the complex clinical course of patients over many years of follow-up would be an enormous undertaking. However, "phase II" or historical data on the costs and outcomes of care associated with each of these two treatment regimens would allow for a more tailored approach. But perhaps the first question that should be answered in designing an economic analysis to accompany a clinical trial is whether the resulting data are likely to be important. This study does not fulfill one of the main criteria for judging the appropriateness of including an economic analysis—large resource consequences. Fewer than 6000 cases of stage III or IV endometrial cancer occur annually in the United States, of which only a portion would be appropriate for the alternative treatment strategies evaluated in this protocol. Therefore, although the clinical question posed by this protocol is appropriate and important, the aggregate economic consequences of choosing one treatment approach over the other may not be of sufficient magnitude to justify the investment in a prospective economic analysis conducted alongside the clinical trial. [Monogr Natl Cancer Inst 19:17-19, 1995]

In planning an economic analysis to accompany a randomized clinical trial, one of the first questions that must be answered is how much economic data to collect. The answer to this question will depend on the perspective of the analysis. Most commonly, analyses are performed from the perspective of society or the payer. The relevant costs, then, will include, at a minimum, the direct medical costs incurred. While theoretical arguments can be made for including direct nonmedical costs and indirect costs

in analyses performed from a societal perspective, in practice, these costs are rarely tabulated in cost-effectiveness analyses of medical interventions.

In deciding which direct medical costs to collect, it is important to remember that, for the purposes of a cost-effectiveness analysis, it is not necessary to characterize the total direct medical costs associated with each treatment, but rather to estimate the incremental costs of treating patients with one strategy compared with the other. There are several ways to estimate this difference. One way is to collect complete economic data on all patients in both arms of the trial followed until death and to subtract the less costly strategy from the more costly strategy. Alternatively, one can limit collection of data on costs to categories of resource use that are likely to differ between groups and/or to periods of time during which treatments diverge between arms. It is probably reasonable to take complete data collection as a starting point in designing an economic analysis, however, and for the clinical researcher and economist to work together to determine whether this strategy is both optimal and practical.

The primary rationale for collecting comprehensive, direct medical cost data is that initial therapy may affect an array of early and late clinical and economic outcomes. And it is often difficult to know ahead of time what those consequences will be. The certainty of knowing that any treatment-related late differences in resource use will be captured is bought at a price, however. If, in fact, resource use later in the course of the disease, for example, is *not* related to initial treatment assignment, the random variation in these data will diminish the precision with which early treatment-related differences are measured. Consequently, the study will have less power to detect and to estimate the differences of real interest.

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The same argument applies to the decision to collect data on resources not directly related to the treatments being evaluated in the trial. For example, in a trial comparing two surgical approaches to treat a localized malignancy, collection of data on the costs of adjuvant chemotherapy is optimal if differences in these costs are related in some way to the specific surgical treatment received. Otherwise, the collection of these costs not only is inefficient but also may compromise the primary goal of the economic analysis, i.e., to generate a precise estimate of the difference in costs between the two surgical strategies.

Practical considerations also enter into deciding on the proper scope of the data collection effort. Collection of complete information on medical resource use until death of all trial subjects may be possible when the median survival is short (e.g., in a study of patients with metastatic non-small-cell lung cancer). Complete data collection will not be possible when survival is expected to be long, however (e.g., in a study of patients with breast or testicular cancer).

Turning now to the protocol under consideration, a study of whole abdominal radiotherapy compared with combination chemotherapy in advanced endometrial cancer, how might we use what we know about these treatments to design an economic analysis that is both comprehensive and efficient? It is immediately apparent that these treatments will consume a complex set of resources that will differ substantially between groups. A comparison of the costs of radiotherapy and chemotherapy per se would fail to capture a number of likely differences in the resources consumed in the initial treatment of the two groups. For example, while the radiotherapy patients will be treated, at least initially, as outpatients, some or all of the chemotherapy will probably be given in the inpatient setting. And, since the duration of active therapy in the radiotherapy group is much shorter than that in the chemotherapy group, the number of visits to the physician and laboratory tests performed in the first 6 months after randomization would be expected to be higher in the chemotherapy group.

Second, the pattern of toxic effects, and, hence, the resources consumed in treating them, are likely to differ between groups. The radiotherapy-treated patients will probably experience higher rates of hospital admission for gastrointestinal toxicity, while the chemotherapy-treated patients will be more likely to develop infectious complications resulting from myelosuppression. The frequency and nature of late toxic effects may also be influenced by the initial treatment strategy. Treatment-related bowel obstructions, for example, might result in substantial, late economic consequences in the radiotherapy-treated group, while cardiomyopathy might be a rare but costly consequence of chemotherapy with doxorubicin.

Third, initial therapy might affect the costs of follow-up. If radiotherapy results in treatment-related bowel obstructions, it may prompt more evaluations for recurrent disease. Additional CA-125 determinations, abdominal imaging studies, and so forth might be performed in this group even if rates of recurrence and survival are identical.

Finally, even the costs of caring for patients who do have disease recurrence could be influenced by the initial treatment regimen. For example, since pelvic radiotherapy may compromise the ability of patients to tolerate the myelosuppressive

effects of later palliative chemotherapy, rates of use of costly hematopoietic growth factors might be higher in this arm.

Clinical judgment thus suggests that we may need to collect complete data on all the direct costs associated with initial treatment, short-term toxic effects, long-term toxic effects, and treatment of recurrent disease. Since the median life expectancy in these patients is measured in years, not months, we are left with the conclusion that the economic analysis must be not only very comprehensive but also of long duration. Before such a massive and protracted data collection effort is undertaken, conclusive evidence that it is really needed to estimate the difference in costs between these two treatments would be reassuring. In addition to clinical judgment, this evidence might include historical or pilot data on resource consumption and frequency of relevant clinical outcomes of care associated with each of these treatment regimens.

In much the same way that phase II data on treatment response are essential in planning an efficient and powerful phase III trial, prior data on the economic consequences of the strategies being compared in a clinical trial allow the design of an efficient and powerful economic analysis. In particular, the economic analysis can be designed to concentrate prospective data collection on those costs and types of resources found in pilot studies to differ most between the two treatment groups. For example, if data from phase II studies or case series of a group of patients treated for endometrial cancer with radiotherapy and another group treated with chemotherapy indicated that, among patients with disease relapse, the number of hospital days and clinic visits during the last 3 months of life were similar in the two groups, it might be reasonable to omit collection of data on the costs of terminal care from the design of the economic analysis for the randomized trial. The investment of time and money in the collection of pilot data could result in savings in the long run by allowing a more tailored approach to collection of economic data in the randomized trial itself.

In one particularly elegant application of this approach, the cost-effectiveness analyst for a large, prospective, randomized trial of cholesterol-lowering therapy after myocardial infarction constructed a cost-effectiveness model during the planning stages of the trial (1). This model was used to identify the clinical and economic parameters to which the cost-effectiveness ratio was most sensitive. The trial was then designed so that the resources expended on collecting specific data items would be proportional to the resulting reduction in the variance of the cost-effectiveness ratio.

It may be appropriate to close this brief discussion of how much cost data to collect in a trial by raising what should really be the first question: Should an economic analysis be built into a given trial at all? Drummond and Stoddart (2) have identified the following criteria for determining the value of including economic analysis in specific clinical trials:

- 1) Results of the trial are likely to be influential in deciding future patterns of care, and this is likely to be the last trial.

- 2) Resource consequences are large because (a) the unit cost difference between alternatives is suspected to be large, (b) alternatives are radically different, or (c) the size of the patient population to be covered is large.



3) Resource considerations are felt to be prominent by clinical researchers, the research-funding body, or those who fund health care.

Does this study fulfill these criteria? This is a well-designed clinical trial that compares two treatment strategies for a defined population in which there is currently no entrenched standard of care. Consequently, it seems likely that the results of this trial will be influential in deciding future therapy. The fact that a trial is likely to have a significant clinical impact, however, does not necessarily imply that it will have large resource consequences. Fewer than 6000 cases of stage III or IV endometrial cancer (International Federation of Gynecology and Obstetrics classification) occur annually in the United States, of which only a

portion would be appropriate for the alternative treatment strategies evaluated in this protocol.

Therefore, although the clinical question posed by this protocol is appropriate and important, the aggregate economic consequences of choosing one treatment approach over the other may not be of sufficient magnitude to justify the investment in a prospective economic analysis conducted alongside the clinical trial.

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# Relationship Between Dose Schedule and Charges for Treatment on National Wilms' Tumor Study-4. A Report From the National Wilms' Tumor Study Group

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National Wilms' Tumor Study-4 was designed to evaluate the efficacy, toxicity, and cost of administration of different regimens for the treatment of Wilms' tumor. The charges for treatment with dactinomycin and doxorubicin administered by two different schedules were calculated using current charges in Buffalo, N.Y. An annual savings of approximately \$779 259 could be achieved by the use of the short, pulse-intensive (i.e., single-dose) treatment regimens for all children with Wilms' tumor of stages I-IV/favorable histology. The pulse-intensive administration schedule for the treatment of children with Wilms' tumor permits administration of chemotherapy at a substantially lower total treatment cost. [Monogr Natl Cancer Inst 19:21-25, 1995]

Wilms' tumor is the most common malignant renal tumor in children and adolescents. The annual incidence rate of this tumor is 7.5 cases per million children younger than 15 years. In 1990, approximately 400 new cases were diagnosed in the United States (1).

Abnormalities within at least two chromosomal segments, 11p13 and 11p15, have been identified in the tumor tissue of some children with this tumor. Germ-line mutations within 11p13 have been identified in children with the syndrome of Wilms' tumor, aniridia, and genitourinary malformations and in those with the Denys-Drash syndrome. Children with aniridia, hemihypertrophy, and the Beckwith-Wiedemann syndrome have an increased risk of developing the tumor.

Several different histologic patterns of Wilms' tumor are recognized and include a triphasic histology with or without anaplasia, clear-cell sarcoma of the kidney, and malignant rhabdoid tumor of the kidney. Approximately 89% of the tumors are of typical histology without anaplasia, 5% are anaplastic, 2% are clear-cell sarcomas of the kidney, and 3% are rhabdoid tumors of the kidney (2).

Those children who present with unilateral tumors and do not have hematogenous metastases have stage I (52%), stage II (24%), or stage III (24%) disease. Those who present with hematogenous metastases (stage IV) represent approximately 15% of all patients. Approximately 6% of all patients present with bilateral renal tumors (stage V).

Treatment of Wilms' tumor patients includes nephrectomy for all patients with unilateral tumors, combination chemotherapy for all patients, and radiation therapy for those with stage III or stage IV tumor. The chemotherapy regimen for patients with Wilms' tumor of stage I or II includes vincristine and dactinomycin, and that for patients with stage III or IV includes vincristine, dactinomycin, and doxorubicin (3).

National Wilms' Tumor Study-4 was a randomized clinical trial designed to test the efficacy and toxicity of a new schedule of administration of dactinomycin and doxorubicin and different total lengths of treatment. The new schedule for drug administration was based on experimental (4) and clinical (5-8) data suggesting that a single-dose (pulse-intensive) schedule was as effective as, and less toxic than, the conventional fractionated (standard) schedule of administration. By requiring fewer intravenous drug injections, the single-dose schedule would also cost less to administer, unless this schedule of drug administration was ineffective or produced a substantial increase in the number of days of hospitalization for the treatment of toxicity. Neither outcome was anticipated on the basis of the experimental models.

## Methods

After all patients completed a preoperative assessment, which was to include radiographic imaging of the kidneys, inferior vena cava, and lungs, they underwent an initial nephrectomy. The histology was categorized as favorable.

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*See "Notes" section following "References."*

anaplastic, or clear-cell sarcoma of the kidney. A surgical-pathologic staging system (3) was employed. Patients with tumors of stages I-III had disease confined to one kidney, with varying degrees of local residual disease. The disease in patients who presented with hematogenous metastases was designated as stage IV, and that in patients who presented with bilateral renal tumors was designated as stage V.

Patients with Wilms' tumor of stage I/favorable histology or stage I/anaplastic histology were randomly assigned to receive vincristine and dactinomycin by standard (regimen EE) or pulse-intensive (regimen EE-4A) schedules (Fig. 1). The total duration of treatment was 25 weeks for those receiving standard therapy and 18 weeks for those receiving pulse-intensive therapy.

Patients treated with regimen EE received dactinomycin at 15 µg/kg per dose for 5 days by intravenous push, beginning within 5 days after nephrectomy (during week 0) and then at weeks 5, 13, and 24. They received vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, and then on the 1st and 5th days of each 5-day course of dactinomycin at weeks 13 and 24.

Patients treated with regimen EE-4A received dactinomycin at 45 µg/kg per dose by intravenous push (maximum dose = 2.3 mg), beginning within 5 days after nephrectomy (during week 0) and then at weeks 3, 6, 9, 12, 15, and 18. They received vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, and then at 2.0 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg) with dactinomycin at weeks 12, 15, and 18.

Patients with Wilms' tumor of stage II/favorable histology were randomly assigned to receive vincristine and dactinomycin by use of standard (regimen K) or pulse-intensive (regimen K-4A) schedules, with a second randomization for treatment to be continued beyond or discontinued at week 21 (regimen K) or week 20 (regimen K-4A) (Fig. 2).

Patients treated with regimen K received dactinomycin at 15 µg/kg per dose for 5 days by intravenous push (maximum single dose = 0.5 mg), beginning within 5 days after nephrectomy (during week 0) and then at weeks 5, 13, and 22. They were administered vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, and then weekly for 6 weeks, starting at week 15. Patients randomly assigned to receive 66 weeks of chemotherapy began additional 5-day courses of dactinomycin at weeks 31, 40, 49, and 58 and additional 6-week courses of vincristine at weeks 24, 33, 42, 51, and 60.

Patients treated with regimen K-4A received dactinomycin at 45 µg/kg per dose by intravenous push (maximum dose = 2.3 mg), beginning within 5 days

after nephrectomy (during week 0) and then at weeks 3, 6, 9, 12, 15, and 18. They were given vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, and then at 2.0 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg) with dactinomycin at weeks 12, 15, and 18. Patients randomly assigned to receive 60 weeks of chemotherapy received additional doses of vincristine and dactinomycin at weeks 21, 24, 27, 30, 33, 36, 39, 42, 45, 48, 51, 54, 57, and 60.

Patients with stage III or IV/favorable histology or stages I-IV/clear-cell sarcoma of the kidney were randomly assigned to receive vincristine, dactinomycin, and doxorubicin by use of standard (regimen DD) or pulse-intensive (regimen DD-4A) schedules, with a second randomization for treatment to be continued beyond or discontinued at week 28 (regimen DD) or week 26 (regimen DD-4A) (Fig. 3).

Patients treated with regimen DD received dactinomycin at 15 µg/kg per dose for 5 days by intravenous push (maximum single dose = 0.5 mg), within 5 days after nephrectomy (during week 0) and then at weeks 13 and 26. They received vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, and then on the 1st and 5th days of each 5-day course of dactinomycin at weeks 13 and 26. The patients received doxorubicin at 20 mg/m<sup>2</sup> for 3 days by intravenous push at weeks 6 and 19. Patients randomly assigned to receive 66 weeks of chemotherapy received additional courses of dactinomycin beginning at weeks 39, 52, and 65, additional doses of vincristine on days 1 and 5 of each course of dactinomycin at weeks 39, 52, and 65, and additional courses of doxorubicin at weeks 32, 45, and 58.

Patients treated with regimen DD-4A received dactinomycin at 45 µg/kg per dose by intravenous push (maximum dose = 2.3 mg), beginning within 5 days after nephrectomy (during week 0) and then at weeks 6, 12, 18, and 24. They were given doxorubicin at 45 mg/m<sup>2</sup> by intravenous push at weeks 3 and 9, doxorubicin at 30 mg/m<sup>2</sup> by intravenous push at weeks 15 and 21, and vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses; then vincristine was administered at 2.0 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg) with dactinomycin or doxorubicin at weeks 12, 15, 18, 21, and 24. Patients randomly assigned to receive 54 weeks of chemotherapy received additional doses of dactinomycin at weeks 30, 36, 42, 48, and 54, additional doses of doxorubicin at weeks 27, 33, 39, 45, and 51, and additional doses of vincristine with dactinomycin or doxorubicin at weeks 27, 30, 33, 36, 39, 42, 45, 48, 51, and 54.

Patients with anaplasia were randomly assigned to receive vincristine, dactinomycin, and doxorubicin (regimen DD-RT) or vincristine, dactinomycin,

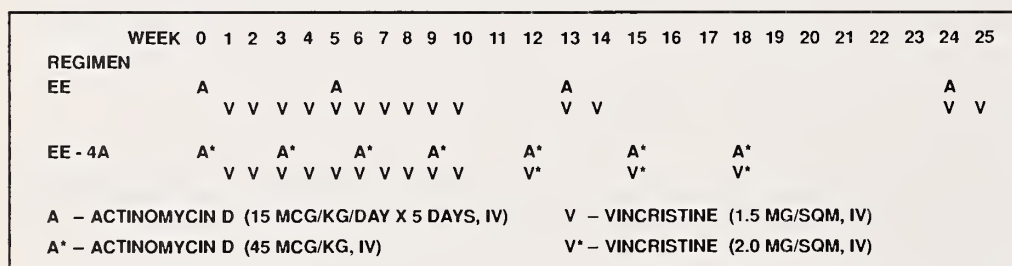


Fig. 1. National Wilms' Tumor Study-4. Treatment randomization for children with stage I/favorable histology or stage I/anaplastic Wilms' tumor. ACTINOMYCIN D = dactinomycin; MCG = micrograms; SQM = square meter; IV = intravenous.

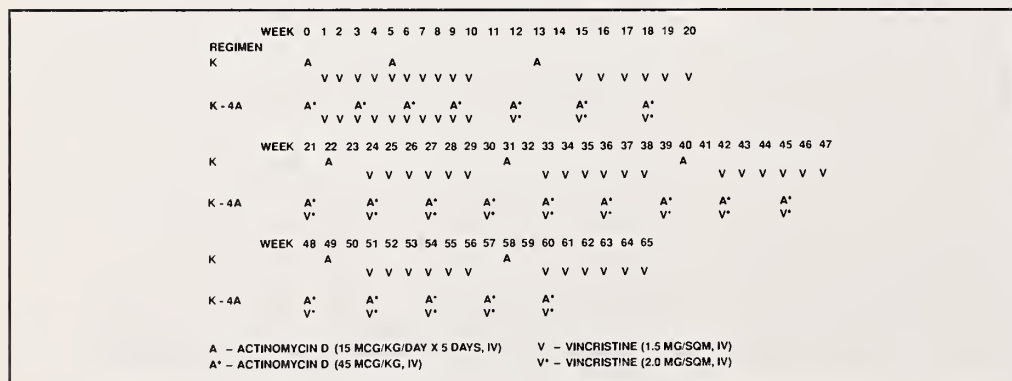


Fig. 2. National Wilms' Tumor Study-4. Treatment randomization for children with stage II/favorable histology Wilms' tumor. ACTINOMYCIN D = dactinomycin; MCG = micrograms; SQM = square meter; IV = intravenous.



WEEK	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
REGIMEN																												
DD		A						D						A					D								A	
		V	V	V	V	V	V	V	V	V	V			V	V												V	V
DD - 4A		A*			D+			A*			D+			A*			D*			A*			D*			A*		D*
		V	V	V	V	V	V	V	V	V	V			V*			V*			V*			V*			V*		V*
XRT																												
WEEK	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47								
DD					D							A						D										
												V	V															
DD - 4A				A*			D*				A*				A*			D*										
				V*			V*				V*				V*			V*										
WEEK	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66									
DD					A						D							A										
					V	V												V	V									
DD - 4A		A*			D*					A*																		
		V*			V*					V*																		

A - ACTINOMYCIN D (15 MCG/KG/DAY X 5 DAYS, IV)

A\* - ACTINOMYCIN D (45 MCG/KG, IV)

D - DOXORUBICIN (20 MG/SQM/DAY X 3 DAYS, IV)

D\* - DOXORUBICIN (30 MG/SQM, IV)

V - VINCISTINE (1.5 MG/SQM, IV)

V\* - VINCISTINE (2.0 MG/SQM, IV)

D+ - DOXORUBICIN (45 MG/SQM, IV)

XRT - ABDOMINAL IRRADIATION

A - ACTINOMYCIN D (15 MCG/KG/DAY X 5 DAYS, IV) V - VINCRISTINE (1.5 MG/SQM, IV)  
A\* - ACTINOMYCIN D (45 MCG/KG, IV) V\* - VINCRISTINE (2.0 MG/SQM, IV)  
D - DOXORUBICIN (20 MG/SQM/DAY X 3 DAYS, IV) D\* - DOXORUBICIN (45 MG/SQM, IV)  
D\* - DOXORUBICIN (30 MG/SQM, IV) XRT - ABDOMINAL IRRADIATION

Fig. 3. National Wilms' Tumor Study-4. Treatment randomization for children with stage III/favorable histology and stage IV/favorable histology Wilms' tumor or clear-cell sarcoma of the kidney of stages I through IV. ACTINOMYCIN D = dactinomycin; MCG = micrograms; SQM = square meter; IV = intravenous.

doxorubicin, and cyclophosphamide (regimen J); both regimens were given for 66 weeks.

Patients treated with regimen J received dactinomycin at 15 µg/kg per dose for 5 days by intravenous push, beginning within 5 days after nephrectomy (during week 0) and then at weeks 13, 26, 39, 52, and 65; vincristine at 1.5 mg/m<sup>2</sup> by intravenous push (maximum dose = 2.0 mg), beginning on day 7 after nephrectomy (week 1) if peristalsis had been established, then weekly for a total of 10 doses, then on the 1st and 5th days of each 5-day course of dactinomycin (starting at weeks 13, 26, 39, 52, and 65), and then on days 1 and 8 of each 3-day course of doxorubicin at weeks 19, 32, 45, and 58; doxorubicin at 20 mg/m<sup>2</sup> per dose for 3 days by intravenous push at weeks 6, 19, 32, 45, and 58; and cyclophosphamide at 10 mg/kg per dose for 3 days by intravenous infusion over a 45- to 60-minute period, followed by oral or intravenous hydration at a rate of 3000 mL/m<sup>2</sup>/24 hours for 18-24 hours after each dose of cyclophosphamide. The courses of cyclophosphamide were given at the same times as the courses of dactinomycin and doxorubicin, beginning with the 6-week course of doxorubicin and then at weeks 13, 19, 26, 32, 39, 45, 52, 58, and 65.

Physicians' Current Procedural Terminology (9) was employed for defining the physician-patient encounters, procedures, and laboratory evaluations as follows: intermediate, established patient visit (99213); brief, established patient visit (99211); hemogram and platelet count, automated, and manual differential white blood cell count (85023); automated multichannel test, 17-18 clinical chemistry tests (80018); chemotherapy administration, intravenous, push technique (96408); and brief, established patient visit without a procedure. The number of each (a-f) was calculated for each National Wilms' Tumor Study-4 treatment regimen. The cost of an intermediate, established patient visit (I) and a brief, established patient visit (B) included only a physician charge. The cost of intravenous drug administration (D) included only the hospital charge. The beginning of a 3- or 5-day course of chemotherapy on the standard regimens (EE, K, and DD) or the administration of a single dose of dactinomycin or doxorubicin on the pulse-intensive regimens (EE-4A, K-4A, and DD-4A) occurred after an intermediate, established patient visit. The intervening weekly doses of vincristine on the standard and pulse-intensive regimens, the subsequent daily doses of dactinomycin and doxorubicin on the standard regimens, and the evaluation of the complete blood cell count results 2 and 3 weeks after the start of a course/dose of dactinomycin or doxorubicin occurred after a brief, established patient visit. The injection of two drugs by intravenous push on the same day was assumed to be two separate drug administrations. A biochemical profile was obtained at the beginning of each 3- or 5-day course of dactinomycin or doxorubicin on the standard regimens and on the day of administration of each single dose of dactinomycin and doxorubicin on the pulse-intensive regimens. A complete blood cell count was obtained at the beginning of each 3- or 5-day course of dactinomycin or doxorubicin on the standard regimens, on the day of administration of each single dose of dactinomycin and doxorubicin on the pulse-intensive regimens, at week 4 of each 6-week course of vincristine on

regimen K, and weekly for 2 weeks after each course of dactinomycin or doxorubicin on the standard regimens or each single dose of dactinomycin or doxorubicin on the pulse-intensive regimens. The hospital charge for a brief, established patient visit (H) was included only on days when the patient did not have a procedure performed (e.g., intravenous push drug injection). These assumptions yielded the following general equation:

$$\text{Medical cost} = aI + bB + cC + dP + eD + fH.$$

The total medical cost and the difference in total medical costs between the longest standard regimen and the shortest pulse-intensive regimen are as follows:

$$\begin{aligned} \text{EE:} & 4I + 29B + 12C + 4P + 34D + 2H \\ \text{EE-4A:} & 7I + 14B + 21C + 7P + 20D + 7H \\ \text{EE - EE-4A:} & -3I + 15B - 9C - 3P + 14D - 5H \\ \\ \text{K (long):} & 14I + 77B + 30C + 14P + 86D + 6H \\ \text{K-4A (short):} & 7I + 14B + 21C + 7P + 20D + 7H \\ \text{K - K-4A:} & 7I + 63B + 9C + 7P + 66D - H \\ \\ \text{DD (long):} & 11I + 61B + 33C + 11P + 65D + 13H \\ \text{DD-4A (short):} & 9I + 18B + 27C + 9P + 24D + 11H \\ \text{DD - DD-4A:} & 2I + 43B + 6C + 2P + 41D + 2H \end{aligned}$$

Costs were estimated on the basis of charges in effect at a large National Cancer Institute-designated comprehensive cancer center in July 1993 as follows: physician charge for intermediate, established patient visit (I)—\$35.00; physician charge for brief, established patient visit (B)—\$25.00; physician charge for chemotherapy administration, intravenous, push technique (D)—\$37.00; hemogram and platelet count, automated, and manual differential white blood cell count (C)—\$10.12; automated multichannel test, 17-18 clinical chemistry tests (P)—\$29.33; and hospital charge for brief, established patient visit (H)—\$24.00.

The cost estimate was based on patients with Wilms' tumor of stages I-IV/favorable histology and assumed a stage distribution as follows: stage I—47%, stage II—21%, stage III—21%, and stage IV—11% (3). The percentage of patients with Wilms' tumor of stages I-IV/favorable histology was estimated to be 81.4% [100% - (6.2% stage V + 12.4% unfavorable histology)] (3) of the estimated 1991 U.S. incidence of Wilms' tumor of 460 cases (1).

## Results

Employing the assumptions detailed in the "Methods" section, the total medical cost of treatment using the various regimens and the excess cost associated with the use of the standard regimen (EE, K, or DD), based on charges in Buffalo, N.Y., are shown in Table 1.

Table 1. Absolute and differential annual cost of treatment for Wilms' tumor of favorable histology, based on Buffalo, N.Y., charges

Charges: Buffalo	EE	EE-4A	Difference	K	K-4A	Difference	DD	DD-4A	Difference
Cost per patient, U.S. dollars	2409.76	1920.83	488.93	6455.22	1920.83	4534.39	5283.59	2454.21	2829.38
Annual cost, U.S. dollars	424 117		86 051	503 507		353 682	634 030		339 525

On the basis of an annual incidence of 374 cases of Wilms' tumor of stages I-IV/favorable histology (stage I/favorable histology—176 patients, stage II/favorable histology—78 patients, and stages III and IV/favorable histology—120 patients), one can estimate that the annual excess cost of treating patients with stage I/favorable histology disease with regimen EE is \$86 051. The savings is 20% of the total cost (\$424 117) for treating patients with stage I/favorable histology tumors using regimen EE (Table 1).

The annual excess cost of treating patients with stage II/favorable histology tumors using regimen K is \$353 682. The savings is 70% of the total cost for treating patients with stage II/favorable histology tumors using regimen K (Table 1).

The annual excess cost of treating patients with tumors of stages III-IV/favorable histology using regimen DD is \$339 525. The savings is 53% of the total cost for treating patients with tumors of stages III-IV/favorable histology using regimen DD (Table 1).

Using these figures, the total annual savings achieved with the short, pulse-intensive regimens is \$779 259, representing 50% of the annual total cost (\$1 561 655) for treating patients with Wilms' tumor of stages I-IV/favorable histology using the standard regimens EE, K, and DD (Table 1).

Because there were no significant differences in the number of days of hospitalization for toxicity (EE versus EE-4A; K versus K-4A; DD versus DD-4A), the costs for treatment of toxicity were not estimated. Nonmedical costs were not estimated.

## Discussion

National Wilms' Tumor Study-4 was initiated in 1986 to evaluate the efficacy and toxicity of standard and pulse-intensive regimens for the treatment of children with Wilms' tumor and concurrently to reduce the cost of treatment through the use of a novel treatment schedule.

The pulse-intensive regimens were developed on the basis of laboratory data that demonstrated that a larger total dose of drug could be given using a single-dose schedule, rather than any of several consecutive-day schedules, for drug administration (10). In addition, when administered using a single-dose, as compared with a daily, divided-dose, schedule, dactinomycin was shown to be more effective for the treatment of the experimental tumor, Ridgway osteosarcoma (4). Skipper (11) reviewed the experimental data showing the importance of dose intensity in the design of successful treatment regimens for experimental tumors, and Hyrniuk (12) reviewed the clinical data supporting the importance of dose intensity in treatment success.

A model was developed to facilitate the estimation of the costs of treatment with the various regimens. Inspection of the cost equations revealed that the costs of regimens EE and EE-4A were very similar. By contrast, the standard regimens K and DD were considerably more expensive to administer than were the corresponding pulse-intensive regimens. The total annual cost for treating patients with Wilms' tumor of stages I-IV/favorable histology was dominated by the marked difference in cost of regimen K, compared with regimen K-4A.

It is difficult to directly compare the costs for medical care in Buffalo with those in the United States as a whole. The practice expense modifier of the Geographic Practice Cost Index by Medicare Carrier Locality for Buffalo and the surrounding counties in western New York is 0.942 (13). The ratio of the fee for an office visit with a pediatrician for an established patient in the Middle Atlantic States (New York, New Jersey, and Pennsylvania) to that in the entire United States is 0.988 (14). Both figures suggest that the savings estimate based on charges in Buffalo is low because of the lower cost of medical care in this region.

No estimate of the nonmedical costs of treatment was made. Others have shown that the cost of work days lost, food, and travel, among others, can be substantial and can exceed that portion of the direct medical costs which must be paid by the family (15-17). These costs would vary in direct relation to the number of days of treatment and, thus, would be related to the sum of  $a + b$ . In all comparisons between standard and pulse-intensive regimens, this sum is greater for the standard regimens. Thus, were we able to estimate the nonmedical costs, the cost savings realized by the use of the pulse-intensive regimens would increase.

Our study demonstrates that the use of pulse-intensive regimens to treat all patients with Wilms' tumor of stages I-IV/favorable histology would result in an annual savings of approximately \$779 000 based on charges in Buffalo.

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# National Wilms' Tumor Study: Economic Perspective

*Martin J. Buxton\**

The National Wilms' Tumor Study poses a question of an essentially economic nature: Can the socioeconomic impact of therapy for Wilms' tumor on the patient's family and society be lessened without compromising the efficacy of therapy? But the only proposed measure of socioeconomic impact appears to be the extent of hospitalization. From an economic perspective, more information is ideally needed from the trial to establish the magnitude of any difference in effectiveness and the magnitude of the difference in costs, so that any trade-off between the two can be assessed. In practice, the extent of the economic data needed at the end of the study will depend on the clinical outcome results and, hence, the nature of the trade-off that will have to be made. If the less extensive treatment is found to be ineffective, economic issues will not come into play. Similarly, if the less extensive treatment is clearly superior in every clinical aspect, the argument for it will probably be persuasive. The interesting situation of a trade-off arises if the less extensive treatment offers clear socioeconomic advantages but has some small clinical disadvantage. In that case, the extent and nature of an array of socioeconomic factors will need to have been measured, not just presumed. There are, of course, many problems associated with collecting and analyzing more comprehensive socioeconomic data in a long trial. This article considers a number of these problems and focuses on six important issues in designing the necessary economic components of future trials. [Monogr Natl Cancer Inst 19:27-29, 1995]

My interest in this topic of economic evaluation within or alongside clinical trials reflects two roles I perform. The first is that of a director of a university-based group of health economists who are actively involved in research on economic evaluation and technology assessment of diagnostic, screening, and therapeutic interventions. The second is as a member of the Health Services Research Board of the United Kingdom Medical Research Council. The Health Services Research Board clearly recognizes the importance of economic considerations in the choice of clinical therapies and has already adopted the position that its presumption is that economic evaluation will normally be required as part of major clinical trials, and it expects trialists who submit any clinical trial proposal explicitly to consider the need for this aspect of evaluation.

Thus, I have strong interests in the undertaking of such studies. However, from both perspectives, I well recognize that there are many practical problems. I therefore welcome this op-

portunity to collaboratively explore the perspectives that economists would bring to the trials supported by the U.S. National Cancer Institute, Bethesda, Md., and to consider the additional useful data that might be collected.

## The Study in Question

The National Wilms' Tumor Study-4 (INT-0070) (1) sets out to address a question posed from an implicitly economic standpoint: Can the socioeconomic impact of therapy for Wilms' tumor, both on the patient's family and on society, be lessened without compromising efficacy? (trial protocol paragraph 2.21).

The trial sets out to establish the effectiveness of a more intensive dosing schedule for the chemotherapy, which simplifies, shortens, and refines the treatment regimen. If the trial can demonstrate equal efficacy without greater toxicity for this new regimen, it will result, it is presumed, in decreased cost for treatment of children with Wilms' tumor.

As the treatment is provided on a mainly outpatient basis, the study sees the key parameter as physician visits: Can these visits be reduced by decreasing the number of treatments per course and the number of treatment courses, without compromising the efficacy of therapy? The only proposed measure of economic effect is the extent of hospitalization. But even for this parameter, the analysis is planned to be based on a 10% random sample stratified by size of institution, with data abstracted from patient charts.

In this context, I would like to consider first whether the nature of the choices involved suggests that a more comprehensive economic evaluation might be valuable and, if so, what the key characteristics of that more detailed evaluation might be.

## Outcomes and Trade-offs

As is usually the case, it would be easier to answer these questions if we knew the clinical outcome of the trial. Using Fig. 1 as a simplified model, let us imagine the possible outcomes. The trial anticipates (indeed presumes) that costs for the new regimen will be significantly lower and seeks to compare the relative benefits of the regimens in terms of relapse-free and overall survival. Assuming for the moment that costs are indeed

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See "Note" section following "Reference."

		Costs		
		Lower	Equal	Higher
Benefits	Higher	Accept		Trade-off
	Equal		Indifferent	
	Lower	Trade-off		Reject

Fig. 1. Position of new technology or regimen.

substantially lower, then the policy implications seem clear if, *and only if*, the new regimen is in no way inferior to the old one in terms of clinical outcomes.

But what would be the clinical policy interpretation of the completed trial if the clinical outcome were marginally, but statistically significantly, poorer? Would no trade-off between reduced costs and reduced benefits be acceptable to patients, families, and clinicians? How would the trial illuminate the nature of that potential trade-off? How much weight should in practice be placed on the desire to reduce the socioeconomic impact on families or society? It is obviously seen as important, or the trial would not have been undertaken, but *how* important? Might not a major reduction in that socioeconomic impact justify a small reduction in expected clinical benefit?

It should be noted that this line of argument is foreshadowed in the statistical section of the trial (paragraph 10.412). However, in the text of the protocol (paragraph 2.21), it is implied that only if the intensive regimen did not in any way compromise efficacy would the lower cost treatment be preferred. It is assumed that if survival difference were statistically significant, any economic advantage, however great, would be irrelevant. To begin to address the question of trade-offs, we would need to know much more precisely what differences in a variety of cost factors need to be traded against what differences in a variety of benefit factors. To properly understand these economic trade-offs, a more detailed economic evaluation will be needed.

## Design Issues for a More Detailed Economic Evaluation

What makes the matter more complex than suggested in Fig. 1 is that the benefits and costs cannot easily be measured as single parameters. Rather, two arrays of factors need to be measured, an array of costs and an array of benefits. But despite the underlying socioeconomic argument, the study focuses almost exclusively on therapeutic outcomes (2-year relapse-free and overall survival rates, relapse rates, disease progression, toxicity, and side effects) that form the main, but not the only, elements of benefit.

The collection of a more extensive array of cost and benefit data would impose additional research costs not only in the form of the direct costs of data collection and handling, but also in the form of the additional problems imposed on the trial by more complex follow-up requirements. How can an appropriate balance be determined?

Preliminary analysis of any available nontrial data about these therapies would be the best starting point to understand more fully what are the patterns of resources used by these children and what are the factors that influence resource use. From this informal analysis, it should be possible to establish what are likely to be the key parameters that are relevant to measuring socioeconomic impact and thus to devise a data collection strategy.

In order to determine how valid the number of hospitalizations might be as a proxy for total cost, it would be useful to estimate the following in advance: 1) the expected differences in costs of hospitalization between the two groups during the 2-year period, allowing for therapy-required hospitalization and hospitalization resulting from toxicity, side effects, and therapeutic failure; 2) for each treatment group, the proportion of total health care costs accounted for by these hospital costs; 3) for each treatment group, the relationship between total hospitalization cost and days of hospitalization; and 4) the degree of interpatient variability for these parameters.

The last point reflects the observation that socioeconomic variables may often be subject to much greater base-line variation than clinical variables. For example, in this particular therapeutic context, I would imagine that a wide variety of non-clinical factors might be expected to affect whether certain types of care are provided on an inpatient, day-patient, or outpatient basis. The type of care might differ according to such factors as the age of the child, the distance (or traveling time) from the child's home to the center, the physical adequacy of the child's home circumstances, the number of siblings, or the work status of the parents. In such a case, the proposed 10% sample for estimation of differences in hospitalization rates (which would cover only some 170 patients during a 7-year period) may well be inadequate. This may be a particular problem if, as is likely, the review of nontrial data suggests that a disproportionate level of total costs is generated by a small number of difficult case subjects who have particular clinical problems. These infrequent case subjects may not be adequately represented in a 10% sample. A key parameter, such as hospitalization, should probably be assessed for all the patients in the trial.

In this context, it may be important also to consider distributional issues. Whom do the socioeconomic factors affect, and on whom do the costs fall? It is conceivable that a different and higher proportion of the costs of the new regimen may fall on the patient's family, perhaps because of the nature of health insurance coverage. It is quite possible to conceive of a situation in which costs overall fall, but the costs to the family increase in absolute terms. This situation could lead to a dilemma where societal and family preferences were at odds.

It is, therefore, most essential to understand the nature of the preferences of the families and their children. In the first instance, the nature of preferences for the different processes of treatment needs to be explored qualitatively to test the validity of the presumption of unambiguous patient preference for the shorter but more intensive pattern of management. Generally, patient preferences are not as obvious as we might presume! It may be necessary to establish the strength of preference for the less intensive regimen, particularly if the study results were to indicate that it, the cheaper and preferred regimen, was asso-



ciated with a small detriment to relapse-free, but not overall, survival. What trade-offs between socioeconomic impact and clinical benefits would parents be willing to make if necessary?

But the arguments for the collection of additional, more detailed data have themselves to be balanced against practical considerations, particularly in a long-term trial such as this. As in all trials, it would be essential here to consider to what extent the artificial context of the trial will affect the resource use (and costs) as well as possibly affect the patients' preferences between the alternative regimens. In such a trial sponsored by the U.S. National Cancer Institute, it may be reasonable to presume that most of the institutions that would normally be caring for these patients would be involved, and these institutions would in the absence of the trial follow similar well-defined management protocols. Thus, in this particular case, the care provided within the confines of a trial may well be very close to that provided in a nontrial context. Even so, although the overall pattern may reflect normal clinical practice, I would want to assure myself, item by item, whether any tests, procedures, or follow-up visits included in the protocol might be excluded in normal practice. For example, imagine a patient successfully treated for a minor side effect on, say, day 26, when the normal routine follow-up is at day 30. In normal practice, would the physician omit the routine day-30 follow-up visit, having already carried out the same tests 4 days earlier during the nonroutine encounter on day 26? And, in the trial, would the same pragmatic response be encouraged, merely permitted, or actively precluded?

Perhaps the strongest reason for caution about the level of detail of data collection in a trial such as the National Wilms' Tumor Study is the long period during which the trial will be active. The statistical calculations suggest that a period of recruitment of at least 7 years is required to answer the primary questions for the whole group (not differentiating by stage or histology). In long trials such as this one, details of the way a particular defined therapy is delivered will change over time. It may become technically feasible to provide more care on an outpatient basis. Structural arrangements may change in the health care system. The framework of financial incentives to providers of care and financial support to families may be modified. The relative costs of drugs, manpower, and capital will likely change. The evaluation strategy will need to be sensitive to such temporal changes. For example, cost data obtained at the beginning of the study may not necessarily be a good indicator of the cost difference found at the end of the trial.

## Summary of Conclusions

The issues raised arise from an economist's consideration of a particular trial of a new chemotherapy schedule for a fortunately rather rare disease in children. But these issues are typical of the problems that might be encountered in establishing the appropriate nature of an economic assessment within any clinical trial.

The following six key areas of concern emerge, and these may serve as a useful, if not necessarily comprehensive, check-

list of issues to keep in mind in designing such economic studies:

- 1) In many cases, the eventual choice of therapy will involve a trade-off, typically of additional clinical benefit for additional cost. Sometimes, as may eventually be the case with the trial examined here, the trade-off will be of reduced socioeconomic impact against marginally poorer clinical performance. To assess these trade-offs, the magnitudes of the differences need to have been firmly established.

- 2) Data on an array of costs and benefit measures are likely to be needed, and preliminary analysis before the trial begins, even using very imperfect data, can help to identify which factors are likely to be important and what level of differences might be expected. Distributional issues (e.g., identifying on whom different elements of cost fall) may be an important factor.

- 3) Because their variability may be greater than that of clinical parameters, it may be inappropriate to measure key socioeconomic parameters for only a sample of patients. Typically, a high portion of total costs will relate to a very small proportion of patients in whom problems occur (such as toxicity, side effects, or therapeutic failure).

- 4) Patient and family preferences for the treatment process in all its aspects need to be determined empirically. Preferences should not be presumed without good evidence.

- 5) Careful attention needs to be paid to whether costs are truly representative of care in a nontrial context and to establish which costs are driven or constrained by the protocol.

- 6) In a long-term study, analysis of costs will need to consider temporal change, since changes in both the specific care technologies and their broader institutional, financial, and social context may have important implications for interpreting the data collected.

All this may make the task of incorporating economics into a clinical trial seem rather daunting, but as the very existence of this trial testifies, the socioeconomic impact of a therapy is of real importance to patients, their families, their physicians, and society in general. Economists need to work with clinicians to ensure that the design of trials provides the necessary basis for obtaining the best possible evidence against which to make the often difficult trade-offs involved in using scarce resources to meet pressing health care needs.

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## Note

I thank participants at the conference and an anonymous reviewer for helpful comments.





# Design and Conduct of a Double-Blind, Placebo-Controlled Trial of Daunorubicin and Cytarabine With or Without Granulocyte Colony-Stimulating Factor in Elderly Patients With Acute Myeloid Leukemia: a Southwest Oncology Group Study

John Godwin\*

From the public health standpoint, acute myeloid leukemia (AML) is an important problem for both young and older adults. AML is the leading cause of cancer death in men aged 15-34 years and the second leading cause of cancer death in women in this age group. This clearly has an impact on loss of life in the productive years. But in terms of the population most affected and of the biology of the disease, the impact is even greater for the elderly patient. Age has been established in many AML treatment trials as a poor prognosis factor. Although there is no consensus as to what age defines an elderly AML patient, those older than 45 years have a lower complete remission (CR) rate than those who are younger. In patients younger than 50 years, the average CR rate is 60%-75%; in contrast, in patients older than 70 years, the CR rate is 35%-40%. Long-term disease-free survival ranges from 25% to 50% in adult AML, depending on the post-remission therapy used and the age of the patient. In November 1991, the Southwest Oncology Group began a study to address the problems of treating AML in the elderly. Many previous treatment trials of AML have included elderly patients as a subgroup of the study analysis, with a larger proportion of young patients. This trial was designed to test the hypothesis that a myeloid growth factor used as supportive care could improve the outcomes in elderly patients with AML. Trials in cancer patients have shown that myeloid growth factors can decrease the number of serious infections and can reduce the length of hospital stay. The use of myeloid growth factors carries the theoretical risk of stimulating leukemia cell growth, since AML blasts are known to express myeloid growth factor receptors. In this trial, patients aged 56 years or older with a morphologically confirmed diagnosis of AML of FAB (French-American-British) class M<sub>0</sub> to M<sub>7</sub>, either de novo or secondary, were randomly assigned to one of two treatment arms. In arm 1, daunorubicin was given intravenously at 45 mg/m<sup>2</sup> on days 1, 2, and 3 and cytarabine was administered at 200 mg/m<sup>2</sup> intravenously by continuous infusion on days 1-7; placebo was also given. In arm 2,

cytarabine and daunorubicin were administered at the same dosage and schedule, but recombinant human granulocyte colony-stimulating factor (rHuG-CSF) was also administered. Treatment with rHuG-CSF was double blind. The specific aims of this trial were to assess the frequency and severity of toxic effects in the two treatment arms; to compare the duration of neutropenia and thrombocytopenia; to compare the total number of febrile days, the number and type of infection episodes, and the number of hospital days; and to correlate biologic parameters, including cell surface immunophenotype, multidrug resistance expression, ploidy, and cytogenetics, with clinical responses. A total of 234 patients have been enrolled in the study, and accrual goals have been met. The results are being analyzed at the time of this presentation. In addition, this study will measure some of the variables necessary to assess the economic impact, i.e., the cost-effectiveness, of the addition of a myeloid growth factor, G-CSF, to the treatment of AML. [Monogr Natl Cancer Inst 19:31-35, 1995]

Leukemia refers to a group of acute and chronic cancers of the hematopoietic system that have in common the uncontrolled proliferation and defective maturation of hematopoietic cells. Acute leukemias account for about half of the total leukemias. They are divided according to the cell line lineage into acute myeloid leukemia (AML) and acute lymphoblastic leukemia. This study concerns AML.

AML is a devastating disease both in personal terms and in its economic impact on society. It is the leading cause of cancer death in men aged 15-34 years and the second leading cause of cancer death in women in this age group. AML clearly has an

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See "Note" section following "References."

impact on loss of life in the productive years. But in terms of the population most often affected and in the biology of the disease, its impact is even greater for the older patient.

The incidence of and mortality from AML increase exponentially with each passing decade of life. This is illustrated in Fig. 1, a composite figure using U.S. mortality data (1) and incidence data from England and Wales (2). Comparison of these data shows that identical trends are present in the incidence of and mortality from AML with advancing age and that these same trends occur outside the United States. (Leukemia shows the least geographic variation of all cancers.) The data in Fig. 1 indicate that the major impact of AML is on the elderly population.

## Background: Leukemia Treatment Trials and Biology

Although AML occurs most often in older patients, clinical trials of AML therapy have disproportionately represented younger patients. Many such trials have consistently shown that age is a poor prognosis factor. Although there is no consensus as to what age defines an elderly AML patient, patients older than 45 years have a lower complete remission (CR) rate than those who are younger. Large clinical trials of modern AML treatment indicate that in patients younger than 50 years, the average CR rate is approximately 60%-75%; for those aged 60-69 years, the CR rate is 55%; for those 70 years old or older, the CR falls to 35% (Table 1). This difference is very likely due to a combination of "disease" and "host" factors. When we consider the host, elderly patients are more likely to have other chronic diseases that have an impact on their ability to tolerate the intensive AML chemotherapy treatments. The blood cell counts of the elderly patient may recover more slowly after chemotherapy because the regenerative capacity is decreased in the bone marrow. Several studies indicate that one of the reasons for the poor prognosis in patients older than age 50 years is poor tolerance for the treatment, as evidenced by a higher death rate during treatment as a result of complications, such as infection or drug toxicity (2-4). On average, 10% of patients under the age of 50

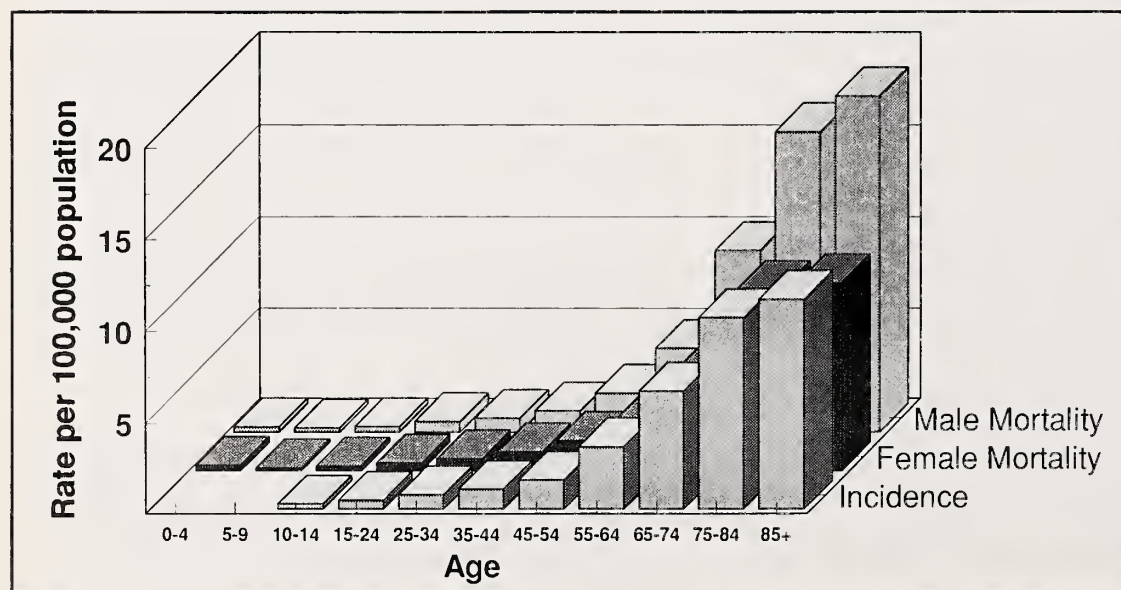
**Table 1.** Average results from standard therapies for AML using a combination of daunorubicin and cytarabine\*

Age, y	CR, %	Induction death, %	Drug resistance, %
<60	70	10	20
60-69	55	20	25
≥70	35	35	30

\*As reported by Peter A. Cassileth, M.D., to the Southwest Oncology Group.

die during induction therapy for AML, whereas induction deaths are 35% in patients 70 years old or older (Table 1). Infection is responsible for the majority of induction deaths in both age groups. Drug toxicity during induction may be reduced by decreasing the dose of anthracycline chemotherapy in patients older than 60 years (5). However, attenuated chemotherapy regimens that reduce doses of all drugs have not improved survival outcome in older patients with AML. In a Southwest Oncology Group (SWOG) phase II study (SWOG-8561), patients 50 years old or older were given V-TAD, a regimen with reduced doses of cytarabine and daunorubicin with etoposide added. The results of SWOG-8561 showed an increase in the number of induction cycles needed to achieve CR, and the overall CR rate of 42% in the V-TAD study was no better than historical results of 40%-48% in the large studies of treatment in older patients (Bigelow CL, Kopecky K, Files JC, et al.: manuscript submitted for publication).

In addition to host factors, the biology of leukemia in the elderly may be different. One difference in clinical behavior is evidenced by high primary treatment failures in the elderly. Leukemia cells that bear the CD34 antigen (stem cell phenotype marker) or the multidrug resistance gene product appear to be inherently more resistant to treatment. Dr. Cheryl Willman and colleagues from the SWOG have analyzed bone marrow taken from patients prior to treatment for the presence of the multidrug resistance marker MRK16 and for the stem cell phenotype CD34. These investigators compared two recent SWOG studies



**Fig. 1.** Average annual mortality from and incidence of AML by age group. U.S. mortality rates: 1969-1977. Incidence rates from England and Wales: 1983.



(SWOG-8600 and SWOG-9031) for the presence of these markers (Willman C, Leith CP: unpublished results). In the SWOG-8600 study, the median age of the patients enrolled was 50 years; in the present study, SWOG-9031, the median age was approximately 68 years. In the SWOG-8600 study, 16% of AML pretreatment samples were found to be CD34<sup>+</sup>/MRK16<sup>+</sup> compared with 46% in the SWOG-9031 study, indicating a higher frequency of expression in the older patient population (Table 2). Another factor in the biology of AML in the elderly is that many patients present with leukemia evolving from a prior myelodysplastic syndrome. Some authors indicate that even apparent "de novo" leukemia in elderly patients often has come from preceding myelodysplastic diseases, as suggested by finding morphologic changes referred to as "background dysplasia" in bone marrow examinations (6).

Because of the difficulties in treating elderly patients with AML, some have suggested a conservative approach with treatment based on symptoms. However, Löwenberg et al. (4) reported a decrease in survival among patients randomly assigned to receive supportive care with attenuated chemotherapy to control symptoms when compared with standard induction. On the basis of these and other data, most authors recommend intensive therapy for elderly patients with AML (7). In view of these issues, the problem of AML in the elderly should be addressed in trials specifically designed for this patient population. New strategies to improve the outcome of treatment of AML in the elderly patient can productively focus on issues involving the initial phase of treatment (induction), since many of the elderly patients fail to complete this portion of their therapy when compared with younger patients. The availability of colony-stimulating factors (CSFs) offers the possibility of having an impact on the long-term survival of elderly patients by accelerating marrow recovery and reducing death from such complications as infection during induction therapy.

## Background: Growth Factors

CSFs are members of the family of hemolymphopoietic growth factors. They are characterized by their capacity to stimulate several cellular activities, including proliferation and differentiation. They also stimulate functions of the fully differentiated cell (8). The cloning and expression of the myeloid

growth factors recombinant human granulocyte-macrophage CSF (rHuGM-CSF) and recombinant human granulocyte CSF (rHuG-CSF) have allowed their use in clinical trials. A number of trials have used G-CSF or GM-CSF as an adjunct with standard chemotherapy regimens for the treatment of solid tumors. These studies (9,10) have shown significant shortening of the neutropenic nadir and a decrease in infectious complications. Other studies (11,12) have also shown that rHuG-CSF can accelerate hematopoietic recovery after bone marrow ablative therapy and autologous bone marrow transplantation. Although the time to the first neutrophil recovery may not be shortened, the time to an absolute neutrophil count of greater than 500 cells/ $\mu$ L is consistently less in those patients given rHuG-CSF or rHuGM-CSF (11,12). In a group of patients with refractory malignancies, G-CSF reduced the duration of antibiotic use and accelerated recovery of neutrophil counts at chemotherapy doses usually requiring autologous bone marrow rescue (13). In addition to shortening the time for bone marrow recovery, G-CSF affects mature neutrophil function, which may be beneficial in decreasing the occurrence and severity of infection. G-CSF promotes the oxidative metabolism of neutrophils, increases antibody-dependent cell-mediated cytotoxicity, and promotes chemotaxis (14).

Before giving CSFs in clinical trials of AML therapy, one has to address the potential risks. Leukemia cell lines express receptors for both GM-CSF and G-CSF, and their growth can be supported in vitro by these factors (15). In one in vitro study, G-CSF promoted differentiation of leukemia blasts and did not support long-term growth of blasts, in contrast to the capacity of GM-CSF to sustain blast cultures (16). The in vitro data highlight the concern for leukemia cell regrowth when myeloid growth factors are used during clinical trials of AML therapy. In clinical trials of AML therapy, treatment with myeloid CSFs has usually been after chemotherapy-induced bone marrow aplasia, to diminish the possibility of leukemia cell proliferation and regrowth. This approach utilizes the growth factor predominantly as supportive care. Another strategy is to use the CSF to stimulate the quiescent leukemia cells and to recruit them into chemotherapy-sensitive proliferating cells. In such trials, the growth factor is given before the chemotherapy, and the CSF may be continued during and after chemotherapy treatment. This approach uses the growth factor as a chemotherapy modifier and is a strategy of treatment intensification.

Preliminary data are now available from several uncontrolled and controlled trials using G-CSF or GM-CSF in AML therapy. In one early trial reported by Ohno et al. (17) from Japan, 108 patients 13-69 years old with relapsed or refractory acute myeloid and lymphoid leukemias were randomly assigned to receive G-CSF after their induction therapy. There was no statistically significant difference in the percentage of blasts in the bone marrow at 21-40 days in the G-CSF group versus the control group. Treatment with G-CSF accelerated the granulocyte recovery and reduced the number of documented bacterial infections. There was no significant difference in the remission induction rate.

In a trial conducted by the Eastern Oncology Group (ECOG) in the elderly, 118 patients aged 55-70 years with AML were randomly assigned to receive GM-CSF or placebo after induc-

**Table 2.** Preliminary biologic data on drug resistance: comparison of AML in elderly patients and AML in adults under the age of 65 years for biologic markers of drug resistance\*

	AML in elderly patients: SWOG-9031, % positive	AML in adults <65 y old: SWOG-8600, % positive
Total CD34 <sup>+</sup>	61	44
CD34 <sup>+</sup> /MRK16 <sup>+</sup>	46	16
CD34 <sup>+</sup> /MRK16 <sup>+</sup> of the total CD34 <sup>+</sup>	75	42

\*CD34 = progenitor cell surface marker; MRK16 = marker for MDR1, multidrug resistance gene 1 product. Leukemia cells that bear the CD34 antigen or the multidrug resistance gene product appear to be inherently more resistant to treatment. Data presented by Cheryl Willman, M.D., and co-workers to the Southwest Oncology Group.

tion chemotherapy (18). The investigators demonstrated accelerated recovery of neutrophils. Time to absolute neutrophil count of greater than 1000 cells/ $\mu$ L was 12 days on the treatment arm versus 18 days on the placebo arm ( $P < .001$ ). They also found a difference in treatment mortality (13% on the G-CSF arm versus 21% on the placebo arm), but this difference was not statistically significant. Although there was no significant difference in the CR rate (61% for GM-CSF versus 46% for placebo), there was a significant difference in the median survival time for assessable patients: a survival time of 325 days in the GM-CSF group versus a survival time of 135 days in the placebo group ( $P = .035$ ).

In a similar study, the Cancer and Leukemia Group B (CALGB) reported 379 elderly AML patients (>60 years old) randomly assigned to receive either placebo or GM-CSF (19). In contrast to the ECOG study, this study showed no difference in induction deaths: 20% in the GM-CSF arm versus 17% in the placebo arm. There was no difference in survival time between the two arms.

Studies to date indicate that regrowth of leukemia cells is not a limiting factor in AML trials and demonstrate that myeloid CSFs can be given to patients with AML without undue toxicity or adverse effects (20). The benefit of CSFs in AML therapy is yet to be established, however, and their role and strategies for use require further study.

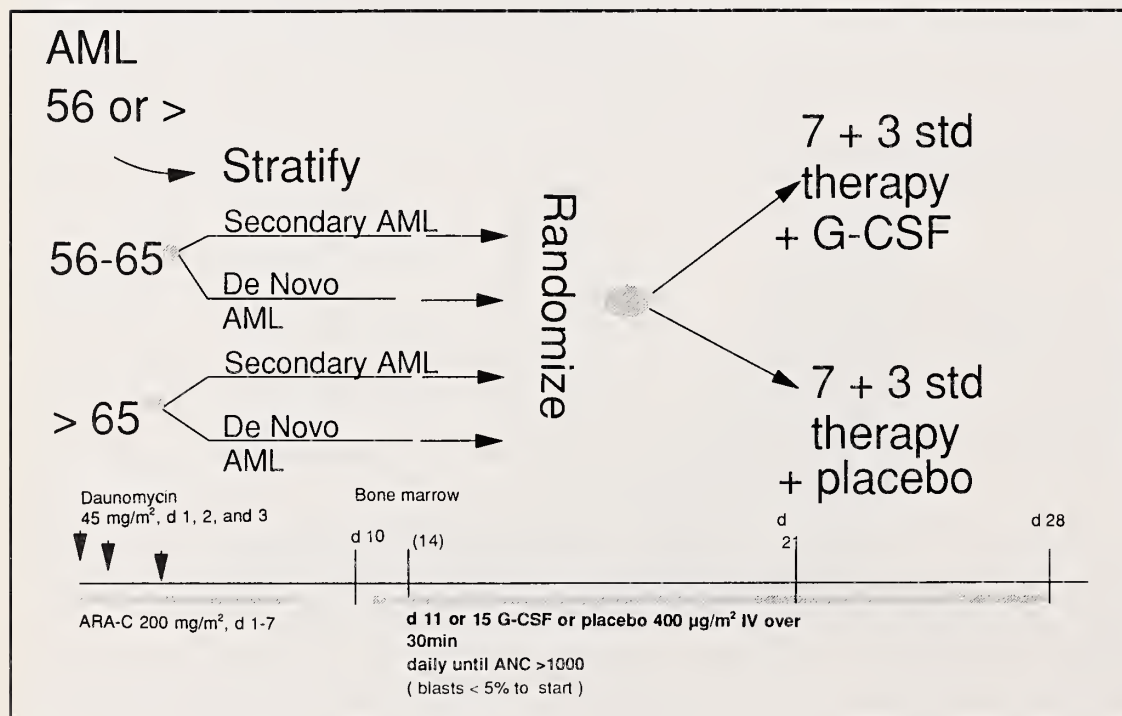
## Methods: Design and Conduct of SWOG-9031 Clinical Trial

This study, SWOG-9031, was proposed to address some of the issues of treating AML in the elderly. The study gives rHuG-CSF after chemotherapy-induced ablation of bone marrow blasts to minimize the possibility of regrowth of leukemia cells. The strategy is to utilize rHuG-CSF as an agent to ac-

celerate bone marrow recovery and to stimulate mature neutrophil function. This strategy may reduce induction deaths from infection and increase the CR rate. Other benefits to the patient may be achieved, including shortening of the hospital stay or reduction in the duration of antibiotic use.

The trial began in November 1991; accrual was completed by February 1994. Eligible patients had a morphologically confirmed diagnosis of AML with FAB (French-American-British) class  $M_0$  to  $M_7$ , based on bone marrow aspiration and biopsy. Patients had reached their 56th birthdays and had a performance status of 0-3 by SWOG criteria. There was no upper age limit. Patients had normal liver, renal, and cardiac functions, with an ejection fraction of 50% or more. Patients with secondary AML were eligible. We believe this is a critical feature, since the aim of any trial is to be representative of the population, and patients with secondary AML are common in the elderly. Secondary AML was defined as the occurrence of AML following myelodysplastic syndrome or prior chemotherapy or radiotherapy. Patients with blastic transformation of chronic myelogenous leukemia were not eligible. Patients were stratified by age (56-64 years versus  $\geq 65$  years) and by onset of leukemia (secondary versus de novo) (Fig. 2).

At the time of initial registration, patients were randomly assigned to one of two treatment arms, one with and one without rHuG-CSF. Both treatment arms used the same standard chemotherapy ("7 + 3") as follows: daunorubicin at 45 mg/ $m^2$  by intravenous push on days 1, 2, and 3 and cytarabine at 200 mg/ $m^2$  given by continuous intravenous infusion over a 24-hour period on days 1-7. A bone marrow examination was performed on day 10 of treatment, and administration of placebo or rHuG-CSF was begun in a double-blind manner (Fig. 2). A total of 234 patients have been enrolled in the study, and accrual goals have been met. The results are being analyzed at the time of this presentation.



**Fig. 2.** Schematic representation of the randomization and treatment of the elderly AML patients in SWOG-9031. ARA-C = cytarabine; IV = intravenous; ANC = absolute neutrophil count; d = day; std = standard; (d 14) = optional bone marrow if d 10 marrow blasts >5%.



The objectives of the study are as follows: (a) to compare the complete response rates and duration of survival in patients aged 56 years or older with AML when treated with standard doses of cytarabine and daunorubicin, with or without rHuG-CSF; (b) to assess the frequency and severity of toxic effects of the two treatment regimens; (c) to compare the duration of neutropenia and thrombocytopenia, the total number of febrile days, the number of days of antibiotic therapy, the number and type of infection episodes, and the number of hospital days in patients treated with or without rHuG-CSF; and (d) to correlate biologic parameters, including cell surface immunophenotype, multidrug resistance expression, ploidy, and cytogenetics with clinical response.

The evaluation of the study objectives will further our knowledge regarding the efficacy and safety of rHuG-CSF in AML using standard measures of clinical outcome, CR rate, survival, and toxicity. In addition, this study will measure some of the variables necessary to assess the economic impact, i.e., the cost-effectiveness, of the addition of a myeloid growth factor, G-CSF, to the treatment of AML. It is important to consider the economic aspect of G-CSF treatment in view of the current uncertain knowledge of efficacy in standard outcomes, such as survival. Economic outcomes are also important in view of the fact that this study's treatment strategy uses the CSF as a supportive care measure, and knowledge of the potential benefits to the patient is needed in this setting.

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# Double-Blind, Placebo-Controlled Trial of Daunorubicin and Cytarabine With or Without Recombinant Human Granulocyte Colony-Stimulating Factor in Elderly Patients With Acute Myeloid Leukemia: Economic Evaluation With Attention to Inpatient and Outpatient Resource Utilization

*Deborah A. Freund, Robert S. Dittus\**

This randomized placebo-controlled trial proposes to determine the clinical importance of adding recombinant human granulocyte colony-stimulating factor (G-CSF) to standard chemotherapy in patients over 55 years of age with acute myeloid leukemia (AML). Although expensive, the addition of this agent could improve patient survival and lower hospital costs by reducing the duration of granulocytopenic episodes and the incidence and severity of infections during chemotherapy.

An economic evaluation is important to consider in this setting because of the cost of the therapy and the unknown effects that the therapy will have on overall costs. If G-CSF is clinically effective, an economic evaluation will be essential to allow health care providers an understanding of the efficiency of resource expenditures for this therapy. Providers and administrators of health care will need to know the gain in health achieved for the financial investment. Without an empirical economic evaluation, arbitrary decisions could be made to divert health care resources to other activities, possibly to the detriment of society. Such a situation is particularly possible where high initial costs make therapies appear more expensive than they are when savings are realized over the short and longer term. Thus, an economic evaluation should be considered.

Adding an economic evaluation to this study forces the study team to confront all of the "classic" design decisions involved whenever an economic analysis accompanies a clinical trial. In this article, we highlight some of the most important of those choices and briefly discuss the trade-off in measurement issues and design characteristics such an economic evaluation might take.

## What Type of Economic Analysis Should Be Used?

An economic evaluation of a drug or chemotherapeutic agent must be tailored to fit the specific aims and study design of the phase III (or other phase) trial. Several approaches could be taken. If cost-benefit analysis was used, a monetary unit (e.g.,

dollars) would have to be attached to survivorship (i.e., a year of life saved would have to be quantitatively valued in dollars). Cost-benefit analysis is not generally recommended because of the difficulty and controversy involved in valuing the benefits of therapy in monetary units (*1*). Cost-minimization analysis would not be appropriate in this study because of the anticipated additional clinical benefit to the patient of adding G-CSF.

The recommended economic analysis would be either cost-effectiveness or cost-utility. In either case, an incremental (marginal) analysis would be appropriate. Both of these types of analyses would measure the incremental costs (numerator of the summary ratio) similarly. The difference lies within the method of valuing the benefit. In cost-effectiveness analysis, the benefit (denominator of the summary ratio) is a measure of a discrete health outcome (e.g., a life saved, a year of life saved, a complication avoided, a remission, etc.). In cost-utility analysis, the benefits are "quality adjusted" in a specific way. Each health outcome state within which the patient could be is weighted by a quality-of-life adjustor (utility). The cost-utility measure thus allows for all of the health outcomes to be combined into a single summary measure and the resulting measure can be compared across other health care programs (*2*).

This study examines the incremental benefit associated with adding G-CSF over and above standard therapy, a natural situation for the application of incremental cost-effectiveness or cost-utility analysis. Therefore, the appropriate technique is incremental cost-effectiveness analysis that asks the economic question, "What is the additional survival or improvement in

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quality of life per extra dollar spent on G-CSF among patients already undergoing chemotherapy for AML?" As we shall see below, there also may be the opportunity to turn this analysis into an incremental cost-utility study.

## Study Perspective

The required data elements in any pharmacoeconomic evaluation vary according to the perspective of the study. Many perspectives can be taken: patient, provider, payor, government, or societal. Each perspective has value, depending on the purpose of the analysis (3). Understanding outcomes from different perspectives may help to illuminate different barriers and/or incentives operating in the delivery of patient care. In general, the societal perspective should be included as the major perspective to understand the overall impact of the therapy if adopted. In this case, all costs and benefits that may positively or negatively affect society are counted. We assume for the remainder of this article that the societal perspective is adopted.

## Generalizability

The process of study sample selection is crucial. For the results of the study to have meaning, the patients to whom the results are applicable must be capable of being delineated. AML is a heterogeneous disease, with age being an important predictor of survival. This study will provide information on patients over 55 years of age. The recognition of such an important variable has prompted the study to use inclusion criteria as a method of controlling for the effect of age. The study will need to carefully monitor the process of enrollment to be able to understand the attrition (and potential biases) from the process of eligibility determination through the follow-up data collection. Because the study design is a randomized controlled clinical trial, the intervention and control groups should be comparable. However, the group to be randomized needs to represent an identifiable population for the results to be generalizable. The study interpretation must not extend to younger patients or for other drug dosages. These are the usual concerns of a clinical study. The economic component also causes generalizability concerns, involving the type of provider system and protocol-induced costs. Each of these issues must be carefully examined to assure the usefulness of study data.

## Study Horizon and Relevant End Points

Before many of the more specific aspects of an economic evaluation of G-CSF can be designed, certain parameters must be set. One of the most important parameters is the study horizon, i.e., how long must patients be followed to accomplish the economic study? Since the most important end point in this study is the duration of survival, a long follow-up time should be provided to determine whether survival time differences between placebo and control are statistically significant. The median survival time among patients managed with standard care is anticipated to be 7 months. Therefore, patients should be followed for at least 2 years to capture important survival data.

Indeed, the study intends to follow patients indefinitely, certainly past 2 years according to the protocol.

Similarly, the appropriate end points to the economic analysis must be identified. This study is designed to evaluate several end points, including total hospital days, frequency and severity of toxic effects, frequency and type of infection episodes, and duration of survival. While infection and toxicity rates are of importance clinically, they are only intermediate end points to the economic analysis. Episodes of infection or toxicity will be so dire that a patient will die, which the survival end point will measure, or the episodes will be less frequent and reflected in reduced costs without an impact on survival. In fact, the number of hospitalizations and days of hospitalization are only intermediate outcomes in an economic study. That is, the days of hospitalization are associated with costs that are accounted for in the cost portion of an economic evaluation. Reduction in days with use of G-CSF become reductions in costs.

## Cost-Effectiveness Ratios

Arguably the most important choices to be made in a cost-effectiveness study relate to the relevant measures of benefits and costs. In all cost-effectiveness analyses, the focus of the analysis is on the computation of a cost-effectiveness ratio (C/E), a measure of the benefits per dollar, or a measure of C/E, where E is the measure of effectiveness and C is the measure of the relevant costs. To calculate the denominator of the ratio in this incremental cost-effectiveness analysis, one computes the difference between the effectiveness that results from giving G-CSF versus not giving it by subtracting the effectiveness in the placebo arm from the effectiveness in the trial arm. Similarly, the numerator is the difference in costs between the two arms (or the additional costs incurred from giving G-CSF versus not giving it).

## Measures of Effectiveness (Benefit)

The measurement of the effectiveness of G-CSF in this trial is linked to the selected clinical end points. Beside survival, other end points that are relevant in an economic evaluation of G-CSF are related to the types of benefits that might accrue to patients (and therefore to society) who receive G-CSF versus those who do not. Even if the study reveals that G-CSF does not extend life, the therapy may improve the quality of life. Quality of life could be improved through a reduction in the frequency or severity of infections, leading to fewer hospitalizations, or an earlier return to work or resumption of daily activities with more vigor.

If the benefit from G-CSF is an improvement in the quality, not duration, of life, then a cost-utility rather than a pure cost-effectiveness study is indicated. In a cost-effectiveness study of G-CSF, the measure of effect in the denominator would be a measure of the number of extra months of survival from G-CSF over and above standard therapy; in a cost-utility study, the measure of effect would be a quality-adjusted life year. Assigning a quality adjustment to the time spent by a patient in a sequence of health states experienced by a patient is usually performed by summing the products of the time spent in various states times the utility of that state. Although quality-adjusted life-years is the most prevalent summary quality measure, there



are others (4). Measuring the utilities of patient health states is a complex endeavor and often very costly. The size of the sample must be large enough to differentiate these measures between the placebo and treatment arms of the study. Torrance (5) discusses the methods including standard gamble, time trade-off, and other procedures.

### Measure of Cost With an Emphasis on Inpatient and Outpatient Use

The calculations necessary for the numerator in an incremental cost-effectiveness or cost-utility study are the same. As suggested by Freund and Dittus (1), one must enumerate all of the direct and indirect costs. Direct costs are all of those that are directly related to the intervention itself. These include costs of all events treated in the hospital and on an outpatient basis, including but not limited to custodial and specialized care, laboratory, x-ray and pharmacy services, procedures rendered, etc. Several problems arise in attaching costs to the services given on each hospitalization stay during a trial. Regarding hospital costs, it is generally easy to get a full list of all such hospital events. However, it is not easy to arrive at an estimation of resource cost. The reasons are multiple. First, hospitals generally apply charges, not costs, to their bills; charges and resource costs deviate because of cross-subsidization of services within a hospital. Second, the costs that hospitals keep are accounting, not economic costs. The differences between accounting and economic costs are important; the latter are meant to measure opportunity costs. Unfortunately, opportunity costs are rarely possible to measure with accuracy. When charges are obtained, appropriate adjustment using a hospital cost-to-charge ratio is indicated. Cost-to-charge ratios should be collected for the department rather than for the hospital as a whole. Generally, hospitals can supply cost-to-charge ratios to investigators. Another method is to use step-down allocation methods as outlined by Drummond et al. (3). While each participating medical center in this clinical trial is presumably following the identical protocol, they will not have the same cost structures. For this reason, costs should be calculated for each medical center using these methods. Sensitivity analysis should be computed using national unit-cost estimates.

Ideally, specific resource consumption will be measured by noting the amount of labor and specific nonlabor resources utilized. If each clinical site is able to provide this measure, then a global monetary valuation can be attached to similar units across sites. The choice of valuation (and relative changes in valuation among resources) also can be examined through sensitivity analyses.

Since the G-CSF trial will be an incremental cost-effectiveness study, special care must be taken to account for those hospital costs incurred in the G-CSF arm of the trial that do not appear in the standard treatment arm. These costs are likely to come from additional tests, personnel time, and the costs of the medicine itself. Reductions in complications or in hospital days for the G-CSF group are counted in the standard way.

A similar principle applies to the enumeration and valuation of outpatient costs, which also are direct medical costs. All outpatient costs for both G-CSF and non-G-CSF should be clearly enumerated and followed for the length of the study. If G-CSF

protects against complications, physician visit rates, for example, are likely to be different between the groups, an example of the substitution of ambulatory for hospital care. The list of important outpatient costs would include visits to all types of physicians and to laboratory and x-ray facilities. It will also include all medications prescribed during the time patients spend out of the hospital, any devices or equipment that are used in their homes, etc. The challenge to acquiring outpatient costs is greater than hospital costs for two reasons. First, generally more different locations of service are present and must be coordinated. Second, with the exception of clinics run by hospitals, physician offices do not usually keep a charge-to-cost ratio or know their costs. These will have to be approximated and subjected to sensitivity analysis.

Direct nonmedical costs for both the G-CSF and non-G-CSF group should be measured; they may be different according to the results of the treatment. Direct nonmedical costs include items such as travel costs to the hospital or home care.

Since one of the positive advantages of G-CSF might be to give the patient more energy, to enable the individual to return to work or engage in more of his or her preferred daily activities, it is useful to digress to discuss indirect measures of cost since these may be very important in a study such as this. Indirect costs include, among other things, measures of differences in work-loss days or in rates or return to work and then value these differences in dollars or another unit of currency. The idea is that one's productivity on the job has a value to society as well as to the individual. (If G-CSF reduces work loss, this is a negative cost; if it increases it, then the costs of the G-CSF arm will be increased relative to the non-G-CSF group.) The easiest way to value the societal impact of work loss is to assume that the value of a patient's time at work is what he would earn on his job. This method is called the "human capital" approach. For this reason, most economic evaluations collect wage data as part of the trial. However, this is a controversial means of measuring productivity costs because it does nothing to correct for labor market discrimination due to sex or race and presumes that individuals who do not work have no value to society. This is likely to be a particularly thorny issue in this trial since many of the patients may not be working because of retirement rather than because of their diagnosis of leukemia. An alternative to the human capital method is the "willingness to pay approach" that values the intervention for individuals by asking them how much they would be willing to pay for to get or avoid certain health outcomes (6). While this method is the more proper, it is also much more difficult to implement and often is avoided.

Protocol-induced costs should at least be noted in any economic evaluation that is attached to pharmaceutical clinical trials. Protocol-induced costs come from those elements of the treatment protocol that are mandated during a trial but which would not be part of standard practice if G-CSF were found cost-effective and disseminated. Most often, protocol-induced hospital costs result from additional laboratory tests and visits that may be necessary to determine if someone is eligible for a trial, for extra outpatient physician visits and tests required during a trial. To approximate what community costs might be, protocol-induced costs should be subtracted from the G-CSF



and non-G-CSF arms before computation of cost-effectiveness ratios.

In the determination of costs, the issues of perspective, marginality, study horizon, and discounting must be considered. The monetization of a resource expenditure will likely be different when viewed from different perspectives. The cost-to-charge ratios are attempts to provide opportunity costs, that which is appropriate from the societal perspective. However, other perspectives (such as that of a payor, e.g., an HMO) may be of interest. The valuation of the costs for one perspective cannot be assumed to be the same for another perspective and each type of resource will need to be examined to ensure the correct valuation for the given perspective. Marginality refers to the resources being consumed to perform the additional test that would not have been otherwise done if the other treatment strategy were used. The average cost of the test would not be the appropriate valuation. The study horizon needs to be determined and evaluated evenly between study groups for both costs and benefits. Costs incurred distant from the intervention may be a result of many processes unrelated to the disease being treated. Patients with longer survival will have greater opportunity to experience these otherwise unrelated costs. Discounting should be considered if the time horizon for the accumulation of benefits and costs extends beyond 1 year. Net costs and benefits should be discounted to their present value using a rate of 3%-8% (3).

## Exploring Uncertainty

A clinical trial will provide information about the group benefit among patients receiving G-CSF compared with the group of patients not receiving G-CSF. However, not all individual patients will have a better outcome with the therapy for which the group does best. Specific patients may be at risk for toxicity or a diminished therapeutic benefit. To date, 212 patients have been enrolled in the study. The ultimate sample size might be too small to estimate impacts across patients with any accuracy. Such treatment uncertainty is common in medicine. When there are not enough data to get an accurate assessment of all of the important economic parameters for each relevant clinical subgroup, decision modeling and sensitivity analysis become useful.

Decision models are commonly constructed using decision trees with or without Markov processes to model recurrent events over time (7).

With a decision tree describing the alternative therapies and outcomes from therapy, uncertainty within any variable can be incorporated by systematically changing the value of the variable and examining the impact on comparative cost-effectiveness between the two therapeutic alternatives. This process is known as sensitivity analysis. Varying many (or all) variables

simultaneously can also be performed; this has been referred to as probabilistic sensitivity analysis (8,9), and new methods for estimating the outcomes from such an analysis are available (10). Incorporating uncertainty into decision models can also be accomplished using network simulation modeling (11,12). A further discussion of modeling frameworks and issues surrounding uncertainty can be found in the study by Freund and Dittus (1) and in the article by Schwartz in this monograph.

## Conclusion

The effectiveness and cost information must be synthesized using an analytical platform allowing for the calculation of a marginal cost-effectiveness ratio. The platform should accommodate the desired perspective(s), allow for the integration of both survival and quality of life, and provide for the incorporation and examination of uncertainty in the input data and results. Ultimately, the quality of the economic evaluation is as dependent on the quality of the cost data as the quality of the effectiveness data. Rigorous attention to the measurement of the costs and to the synthesis of the cost and effectiveness data in this clinical trial will provide the best opportunity to understand the overall clinical and economic impacts of G-CSF.

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# Randomized, Comparative Study of High-Dose (With Autologous Bone Marrow Support) Versus Low-Dose Cyclophosphamide, Cisplatin, and Carmustine as Consolidation to Adjuvant Cyclophosphamide, Doxorubicin, and Fluorouracil for Patients With Operable Stage II or III Breast Cancer Involving 10 or More Axillary Lymph Nodes (CALGB Protocol 9082)

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The prognosis for patients with primary breast cancer involving multiple axillary lymph nodes is poor. Only about 30% of patients remain disease-free at 5 years from diagnosis despite surgery, conventional-dose chemotherapy, and radiation therapy. In nonrandomized studies, the use of high-dose chemotherapy as consolidation therapy after standard-dose induction chemotherapy has resulted in an apparent improvement in disease-free survival rates to over 70%. These results have prompted the National Cancer Institute to sponsor large-scale, multicenter, randomized comparative trials of this strategy. This Intergroup Study (Cancer and Leukemia Group B 9082, Southwest Oncology Group 9114, and National Cancer Institute of Canada MA13) compares two treatment strategies in women with primary breast cancer involving 10 or more axillary lymph nodes. Arms A and B are identical in the use of four cycles of conventional therapy with cyclophosphamide and doxorubicin and fluorouracil, radiation therapy, and tamoxifen. The only difference between the two arms is the dose intensity of the cyclophosphamide, cisplatin, and carmustine given following conventional adjuvant treatment. Arm A dictates bone marrow, peripheral blood stem cell, and hematopoietic growth factor support and frequently requires a prolonged hospital stay with high resource utilization. Arm B, with its less dose-intensive therapy, requires considerably less support to apply the treatment. Because of the high cost of this therapy and the requirement for technology-intensive support, there has been considerable interest in economic outcome assessments. [Monogr Natl Cancer Inst 19:41-44, 1995]

Breast cancer is a common disease affecting approximately 182 000 women annually in the United States, with over 46 000 deaths (1). While adjuvant chemotherapy has demonstrated modest but consistent improvement in long-term, disease-free, and overall survival rates, there are extensive clinical data that demonstrate that the probability of survival at 10 years after diagnosis of breast cancer correlates with the number of involved axillary lymph nodes present at the time of primary surgical management (2). Patients with 10 or more involved axillary lymph nodes have a chance of relapse between 55% and 87% by 5 years and between 70% and 90% by 10 years (3).

It has been recognized that there is a steep dose-response curve for many antitumor agents for both therapeutic and toxic effects (4). Clinical data supporting a steep dose-response effect for chemotherapy have been presented for the analyzed treatment results from a number of clinical trials and demonstrate a major influence of dose intensity on the therapeutic outcome. Hryniuk and Bush (5) analyzed the response and outcome of large trials in terms of the dose intensity planned and actually given. Their findings demonstrated a clear correlation between objective response rate and planned or actual dose received as well as a highly significant correlation between the median survival time of all patients in each study versus remission rate (5).

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High-dose therapy with autologous transplantation for metastatic breast cancer has been investigated since the early 1980s in both phase I trials to demonstrate the maximum tolerated doses of combination chemotherapy regimens and in phase II trials to estimate the efficacy of these treatments (6). Overall response rates ranged from two to 10 times higher than the response rates for conventional-dose therapy in the metastatic setting, with response durations comparable to conventional-dose treatments (6). However, dose-intensive therapy with autologous transplantation was demonstrated to be feasible and safe; therefore, pilot studies were begun to evaluate this treatment strategy in patients with early-stage disease.

Because of the poor outcome with standard adjuvant therapy in selected subsets of women with primary breast cancer, the Duke University Bone Marrow Transplant Program and the Cancer and Leukemia Group B (CALGB) undertook a phase II trial (CALGB Protocol 8782) of high-dose chemotherapy and autologous bone marrow support as consolidation treatment after standard-dose adjuvant therapy (7). In that series, 85 women whose median age was 38 years (range, 23-56 years) underwent primary surgical management (84 with modified radical mastectomy, one with segmental resection). All of the women were demonstrated to have at least 10 positive axillary lymph nodes (median, 13; range, 10-20+) at axillary dissection. Within 8 weeks following surgery, patients were extensively staged, including computed tomography of the head, chest, abdomen, and pelvis; bone scans; bilateral bone marrow biopsies, and a chemistry panel to demonstrate no evidence of metastatic disease. In addition, patients were required to meet cardiac, pulmonary, and renal function criteria prior to beginning standard adjuvant therapy.

Details of that study have been previously published (7). Briefly, adjuvant therapy consisted of four cycles of cyclophosphamide (600 mg/m<sup>2</sup> intravenously on day 1), doxorubicin (60 mg/m<sup>2</sup> intravenously on day 1), and fluorouracil (600 mg/m<sup>2</sup> intravenously on days 1 and 8) (CAF), with cycles repeated every 28 days. This CAF regimen was used to be comparable to the highest-dose arm of a contemporary CALGB trial (Protocol 8541) (8) that was evaluating dose schedules of CAF as standard adjuvant chemotherapy. Bone marrow was harvested after three cycles of CAF; in addition, 65 patients had granulocyte colony-stimulating factor (G-CSF)-primed peripheral blood progenitor cells (PBPCs) collected after the 4th cycle of CAF. All patients then underwent dose-intensive cyclophosphamide, cisplatin, and carmustine (CPA/cDDP/BCNU) therapy with autologous support. Following recovery from the intensive therapy, patients received locoregional radiation therapy and all patients who were estrogen receptor (ER) and/or progesterone receptor (PR) positive or whose ER and PR status were unknown were placed on tamoxifen therapy for 5 years or until relapse.

The results of the pilot study were encouraging. As of May 1, 1992, with a median follow-up of 30 months (range, 16-50 months) after beginning treatment, there was a 79% survival rate and a 72% event-free survival rate. There had been 10 treatment-related deaths occurring at 6-14 months and 12 relapses occurring at 11-28 months. A recent update of that pilot study indicates a 71% (confidence interval, 53%-84%) event-free sur-

vival rate, with an overall survival rate of 78% (confidence interval, 56%-88%) at 5 years (9).

Compared with patients with 10 or more nodes treated on previous CALGB adjuvant studies, these patients appeared to have an improved event-free survival rate (7). However, because of the inherent problems of historical comparisons, a prospective, randomized clinical trial was undertaken to evaluate the role of dose-intensive therapy following standard adjuvant CAF for women with poor-risk breast cancer. This ongoing clinical trial was opened in 1990 and is described as follows.

## Study Objective and Design

The primary objective of CALGB Protocol 9082 is to determine whether adjuvant chemotherapy with four cycles of CAF followed by high-dose CPA/cDDP/BCNU with autologous hematopoietic stem cell support (bone marrow plus PBPC), produces superior disease-free survival and overall survival rates compared with the same CAF adjuvant chemotherapy followed by standard-dose CPA/cDDP/BCNU in patients with stage II or operable stage III breast cancer involving 10 or more axillary lymph nodes. In addition, the study will compare the toxic effects experienced between the two patient groups.

The study design is shown in Fig. 1. Within 8 weeks of primary surgery, patients are extensively studied to determine their eligibility (Table 1) for protocol entry. All patients are required to be seen at a CALGB-approved transplant center to confirm eligibility, to obtain written informed consent, and to reregister (Fig. 1). At the same time, patients are offered participation in the Quality of Life companion study (CALGB 9066). Patients then return to their primary physician for treatment with three cycles of CAF. Following the third cycle, patients are again extensively re-evaluated to confirm ongoing eligibility. Patients return to the transplant center for randomization; those randomly assigned to receive dose-intensive therapy (Arm A) undergo bone marrow harvest prior to the fourth cycle of CAF. Women randomly assigned to receive standard-dose therapy (Arm B) have the option to have marrow stored for future use should they relapse.

Following the fourth cycle of CAF, the transplant patients also undergo three leukopheresis procedures to collect primed (G-CSF) PBPCs. All patients return to the transplant center for treatment on either Arm A or B. Approximately 6 weeks from initiating therapy, when the patient has recovered from the acute side effects of treatment and the hematopoietic function has normalized, patients are again extensively evaluated for evidence of disease. Tamoxifen is begun as appropriate and patients are evaluated for locoregional radiation therapy. At regularly prescribed intervals, patients are seen by their primary physician and evaluated for disease status, toxic effects of therapy, and overall performance status. Quality of Life (Protocol 9066) assessments via telephone interviews are measured at 3, 12, 24, and 36 months following treatment on either Arm A or B.

## Statistical Considerations

The study design is that of a randomized, two-arm clinical trial. The major end points are disease-free survival and toxicity.





**Table 1.** Pretreatment evaluation and eligibility determination\*

General
Signed informed consent
History and physical examination
Performance status
Staging
Bone scan
Computed tomography, head
Computed tomography, chest, abdomen, and pelvis
Bilateral bone marrow biopsies and unilateral aspirate
Mammography
Laboratory
ER/PR determinations
Complete blood cell count with differential and platelet count
BUN/creatinine
Serum electrolytes
Calcium, phosphorus, and magnesium
Liver function studies
Bilirubin
AST/ALT
LDH
Alkaline phosphatase
HIV
Hepatitis B serology
Hepatitis C serology
Cytomegalovirus serology
Herpes simplex virus serology
Functional studies
Pulmonary function studies with diffusion capacity
Left ventricular cardiac ejection fraction
Electrocardiogram

\*BUN = blood urea nitrogen; AST = aspartate aminotransferase; ALT = alanine aminotransferase; LDH = lactate dehydrogenase; and HIV = human immunodeficiency virus.

differences between the two arms. Using a two-sided test at the  $P = .05$  level, there now will be a 90% power to detect an absolute difference in the disease-free survival rate at 5 years of 15% (e.g., 55% versus 70%). An estimated 380 patients per arm will be needed to detect this difference and the total duration of the study is estimated to last 6.67 years (anticipated time of closure, September 1997).

## Current Status

As of March 31, 1995, a total of 515 patients have been registered in this study from 35 Transplant Centers in CALGB ( $n = 24$ ), the Southwest Oncology Group ( $n = 10$ ), and the National Cancer Institute of Canada ( $n = 1$ ). Accrual continues to be rapid, with current registrations averaging 12 patients per month.

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# Economic Evaluation of High-Dose Chemotherapy and Bone Marrow Transplantation for Patients With Breast Cancer of Stage II or IIIA With More Than 10 Positive Lymph Nodes at Surgical Excision

Kevin A. Schulman, Henry A. Glick\*

Several issues related to the design of a multi-year study of the outcome of high-dose chemotherapy with bone marrow transplant for patients with metastatic breast cancer have been discussed. Important considerations include an understanding of the types of data that would be collected through the study period, an assessment of treatment benefits and complications, an understanding of the valuation of differences in resource consumption across treatment arms, and an informed definition of the study population to include in the economic assessment. The resulting analysis will help patients and policy makers better understand the impact of aggressive treatment options for breast cancer patients. [Monogr Natl Cancer Inst 19:45-50, 1995]

The success of treatment of patients with breast cancer of stage II or IIIA (1) with more than 10 positive lymph nodes at the time of surgical intervention has been relatively disappointing to date. Investigators have proposed the use of a new high-dose chemotherapy regimen in an attempt to improve the success of treatment of this disease, with bone marrow transplantation required as supportive therapy. Economic analysis has not been included as a secondary end point for the clinical studies of this therapy (2).

Economic analysis of high-dose chemotherapy and bone marrow transplantation would include an assessment of both the cost and benefits of therapy for treatment and usual-care groups. The following issues are important in the design of an economic study in this population:

- specific economic data elements to be collected,
- duration and intensity of the economic data collection effort,
- calculation of differences in resource consumption across the study arms,
- assessment of the potential treatment benefit, and
- identification of the treatment population.

The succeeding sections of this article address these issues.

## Economic Data Collection

High-dose chemotherapy with bone marrow transplantation support may be relatively resource intensive at the time of initial treatment. In assessing the impact of this therapy on patients, we must understand the resources required for treatment and subsequent care, the timing of resource use by patients, and potential differences in the types of resources used across the study arms. While most high-dose chemotherapy protocols outline a program of rigorous assessment of treatment benefits at periodic intervals, these studies provide little understanding of the additional resources required in the care of these patients beyond their initial protocol-specific therapy. For example, patients who receive high-dose chemotherapy may be re-hospitalized more frequently than patients who receive standard-dose chemotherapy, or one chemotherapy regimen might have increased rates of side effects (pulmonary fibrosis, infection or transfusions) with identifiable resource consumption as compared with another regimen.

In designing an evaluation of this therapy from a clinical economics perspective, we must outline the potential impact of each treatment on patients over time to better address each of these issues. Issues that are not addressed prospectively may result in a bias in the study design or may need to be re-addressed retrospectively. Several conflicts need to be resolved during the study design process. The study should be comprehensive in that it addresses all of the potential economic issues related to treatment, yet it should also be parsimonious in its data collection, so that investigators, coordinators, and patients are not overwhelmed by the data collection effort. The period of the study follow-up should be sufficient to address the

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See "Note" section following "References."



major economic questions, yet short enough to allow the study to be conducted in a reasonable time frame. Potential biases in study design and data collection must be addressed, while "noise" (i.e., random variation in measurement) in data collected cannot be reduced entirely. This process requires extensive planning and discussion between the clinical and economic experts involved in the study.

Investigators will need to determine the data elements to be followed throughout the study period. Hospitalizations are usually one of the first important resource elements to be identified for the economic assessment. In the treatment of patients with breast cancer, many non-hospital resources may be provided to study patients. These resources include home infusion therapies, outpatient treatments, pharmaceutical treatments, home nursing visits, and home hospice visits. These non-hospital-based services may prove especially resource intensive over the prolonged study period.

Collection of economic data may require extensive follow-up with study patients. While the transplant center may have economic data for the initial transplant hospitalization, it may not provide subsequent care to patients and may not have subsequent access to patient records on a routine basis for post-discharge patient care. Economic data collection for patients who receive care at sites other than the transplant center may be especially problematic for patients referred from long distances to specialty treatment centers. Data collection and follow-up for clinical protocols are often not comprehensive. There may be long periods between follow-up visits or contacts, during which time substantial resource consumption may have occurred. This type of follow-up may be appropriate when survival is the only long-term end point of a study. It may not be adequate when study end points include quality-of-life assessment or resources required to care for study patients. Establishing a data collection system for longitudinal data collection for inpatient and outpatient treatments requires an understanding of the types of patients being treated, the plans for providing post-discharge care to study patients, and identification of the specific quality-of-life and resource elements that will be collected for the study.

The burden on the caregiver as a result of the illness is increasingly important to our understanding of the impact of disease on breast cancer patients and their families. Spouses may be required to stay home to help patients through their illness or to accompany patients to physician or nurse visits. Child care may be an important concern to patients and may need to be provided during the periods of acute illness. Direct non-medical costs of care, such as travel to and from specialty referral centers, may also place an additional financial burden on patients and their families.

## Sources of Economic Data

Clinical protocols are often the first source of data for an economic evaluation. Many clinical data elements may be important in an economic evaluation of breast cancer treatment. Such elements include patients' health status at the time of randomization, the manner in which the tumor was detected, demographic information (e.g., age, employment status, income, health insurance status, and marital status) obtained at the time

of randomization, and medical comorbidities. Sometimes clinical protocols document the source of hospital admission for inpatient treatment protocols (i.e., emergency room, elective). They may also record specific diagnostic tests or procedures required before randomization or information on resource consumption for study patients prior to the date of randomization (their use of inpatient or outpatient resources during the past year). However, clinical protocols often do not contain all of the data elements required for an economic evaluation. For example, protocols may record the highest values for laboratory tests but not the number of tests performed. They may record the results of a mammogram or computed tomography scan on a specific treatment day but not the total number of radiologic examinations performed. They may record the discharge date from a hospital but not whether the patient was able to return to work or whether the patient required subsequent care at a nursing home or hospice.

Economic case report forms within the clinical protocol can be developed to document these resource consumption elements for specified time periods. As currently implemented, these forms often record resource consumption by study patients but not the costs of the resources. In the United States, a separate effort can be undertaken to collect patient bills for inpatient and outpatient medical services. "Charge" data may need to be converted to cost data, depending on the perspective of the study (3).

For studies with longer follow-up periods or where patients receive care on an inpatient and outpatient basis, additional data collection mechanisms are often required to follow study patients over time. These mechanisms include the use of administrative datasets and the use of patient self-report of resource items.

Administrative datasets, such as health insurance datasets, can be relatively comprehensive in that they record both inpatient and outpatient resource use. The Health Care Financing Administration has data on resource use for all Medicare-insured patients in the United States. Recently, Medicare data have been made available to investigators to follow resource consumption of patients in clinical trials when research protocols are approved by the Health Care Financing Administration and when consent has been obtained from participating enrollees. Many managed care organizations have begun to use their administrative datasets for economic evaluations of medical services.

The use of administrative datasets for economic evaluation is not without difficulty. These datasets usually lack detailed information on the clinical status of patients, although this may be less important for economic analysis of clinical studies than for observational studies. (In clinical studies, the clinical data collection effort is accomplished directly through the clinical protocol.) Patients in a single clinical protocol may each have different health insurance carriers. (The first 25 patients in one treatment protocol for metastatic breast cancer had 19 different insurance carriers [Schulman KA, Glick HA: unpublished data].) Patients may be lost to the administrative database during the study period, they may lose their eligibility status for specific types of insurance (particularly a problem for patients covered by Medicaid), they may lose their insurance benefits (especially in cases where disability from their illness results in a loss of employment), or they may change their insurance car-



rier during the study period. Administrative datasets that include financial information on patient care are often not available in other countries. Specific administrative datasets in the United States may be relatively underdeveloped in terms of reporting resource consumption elements or costs, especially those of many Department of Veterans Affairs medical centers or of certain staff model managed care organizations.

Administrative datasets may lack information on economically important but uncovered services. This is especially the case with medications, since most health insurance plans do not cover prescription pharmaceuticals. For example, Medicare data could not be used to report on the use of tamoxifen by elderly breast cancer patients. An additional complicating issue is that patients may have multiple insurance carriers that reimburse providers for the same service. Many patients have primary and secondary insurance carriers, including co-insurance for major medical expenses, or Medigap insurance for the deductible expenses and copayments required by the Medicare program. Finally, most health insurance carriers do not yet have mechanisms to provide economic data to clinical investigators on a routine basis for patients enrolled in a clinical trial with an economic end point. Identification of relevant contact personnel at carriers through which to obtain these data is often difficult, and different carriers may have different procedures (and different consent forms) for releasing economic data.

Patient self-report may be an important component for recording resource consumption on a longitudinal basis. Certain data elements can be assessed only by the patients themselves. For example, quality of life, employment status, the extent of disability resulting from breast cancer or its treatment, and the cost of uncovered or out-of-pocket medical expenses usually can be collected only from patients.

To obtain accurate self-report data, frequent contact needs to be maintained with study patients. There may be substantial recall biases by patients in reporting resource elements when data are not collected by study personnel for an extended period; recall biases may be even more severe over the short term for patients who are the most ill, since these patients require the most resources. Contact with patients should be no less frequent than every 2-3 months when patients have a mechanism to help record economic data, such as a patient resource consumption diary. Follow-up may need to be more frequent (monthly or every 2 weeks) when a diary is not used. Patient self-report can be accomplished on an assisted basis through a mail or phone interview or through primary care physicians or by study personnel when providing comprehensive periodic assessment of patients.

With the many diverse sources of data required for an economic assessment of the impact of treatment on breast cancer patients, data collection processes need to be clearly detailed, comprehensive, and readily analyzable. Review of source documents may be important for resource items such as hospitalization (which may be true from both a clinical perspective and an economic perspective), while impossible for other elements (patient preference assessment).

## **Application to Protocols for Patients With Metastatic Breast Cancer**

Many of the issues in the preceding section provide important considerations in the development of an economic protocol for the treatment of patients with metastatic breast cancer. The first step in planning an economic evaluation for these patients would be to construct a model of the sources and types of care that patients would receive over the period of study. Special consideration should be made to identify those resources that may be provided outside the study center. For example, patients randomly assigned to receive conventional treatment may receive subsequent chemotherapy from their oncologist rather than returning to the study center in some protocols. Thus, data collection mechanisms would have to be developed to record all resources used at all hospitals that provide care to study patients, not just those provided at the transplant center.

Once this task is completed, case report forms can be developed to measure appropriate resources for each study period. For example, separate case report forms could be developed for the randomization hospitalization, for outpatient resource use after discharge from the randomization hospitalization, for subsequent re-hospitalizations, and for other types of services, including hospice or nursing home care. Clinical and economic investigators will need to determine the specific resources to be recorded through these efforts. For patients with metastatic breast cancer who are in a trial in which they receive high-dose chemotherapy and bone marrow transplantation, these resources could include blood products, additional breast cancer treatment (including chemotherapy or radiation therapy), and pharmaceutical resources (pain medications or hormonal therapies). This effort may be informed by a pilot study using an administrative dataset to provide information about resource consumption by breast cancer patients over an extended period.

If the study is implemented within a managed care organization or within a health care system that has an administrative dataset for all study patients, the data collection burden on clinical investigators can be reduced given these alternative data collection systems. However, if the protocol is initiated at National Cancer Institute (NCI) cancer centers or NCI Cooperative Group hospitals and is open to all eligible patients, irrespective of health insurance status, the potential to use an administrative dataset to identify resource consumption by study patients is severely limited. Inpatient databases from these centers will usually not provide all the data elements required for the economic evaluation of cancer treatments.

## **Analysis of Resource Data**

Once the data collection strategy has been defined, several different resource consumption measures will be available for each breast cancer patient. Case report forms will record detailed information on individual resource items that were required by study patients. Individual resource items can be analyzed across treatment arms to address specific concerns, such as the number of units of platelets required by study patients in the treatment or control arm of the protocol. However, individual resource consumption items cannot be ag-

gregated within and across treatment arms because resource measures represent unique data elements. For example, bone marrow transplant patients may require more inpatient days to receive their treatment, while control patients may require more outpatient visits to their physician for their chemotherapy regimens. Obviously, the total number of resources required by study patients is not meaningful. Furthermore, it is statistically problematic to compare multiple resource items across study populations without adjusting for multiple comparisons. Instead, these data can be aggregated by developing cost estimates for the individual resource categories recorded for the study. By assigning these costs to each of the individual resource items collected in the treatment protocol, we can assess the difference in resource utilization between the two treatments.

### Avoiding or Delaying Resource Consumption

Treatment protocols are designed to be able to report the difference in outcome between treatment and control groups. Even with high-dose chemotherapy, breast cancer may remain a chronic disease for patients with stage II or IIIA breast cancer. From an economic perspective, the timing of clinical events then takes on additional importance. The cost of each episode of recurrent disease may be equivalent for patients in both the high-dose therapy and usual-care arms of the study, but the timing of these medical events could differ. For example, we may find that clinical events are delayed to some later period for patients in the high-dose treatment group as compared with those in the usual-care group. This is an important distinction, especially when the expected clinical events may be delayed beyond the study period for patients in one arm of the trial (Fig. 1).

This concept of delay is an important consideration for economic analysis. The resource difference across the study arms would be valued differently if we believe that resource use was avoided as compared with merely being delayed. The economic benefit of delayed resource consumption is obviously less than that of avoided resource consumption. Thus, we may

want to ensure that we are able to observe study patients long enough to distinguish between delayed and avoided clinical events. An analysis of avoided versus delayed costs can usually be performed only after the study data are available. We can then look at the cost of time periods, such as the cost of the last 3 months of a patient's life, and can model the observed and predicted costs for study patients adjusted for survival differences across the treatment arms. Even with this analysis, we may still need to project the potential treatment benefits over a longer period (up to a patient's lifetime) to assess the true economic benefits of delayed events.

### Analysis of Treatment Benefit

One of the most unusual features of a treatment protocol, including high-risk treatment strategies such as high-dose chemotherapy, is that patients are asked to undergo a treatment that has a higher initial mortality than usual care with an expectation of later treatment benefits compared with usual care. In most analyses of clinical trials, we look at combined mortality rates from treatment and disease to report the success of therapy. To the extent that there is a trade-off between the initial mortality due to treatment and later mortality due to disease, the usual survival curve methods for assessing treatment effect may not provide patients with all the information needed for an assessment of their treatment choices.

An alternative means of analyzing the treatment benefits is to look at survival on a life expectancy basis by assessing the area under the survival curves for treatment and control patients (4,5) (Fig. 2). The life expectancy method allows us to better assess the effect of the immediate loss due to treatment and to integrate the survival benefits resulting from therapy with this early mortality (Tables 1 and 2).

Another reason for adopting the area-under-the-curve approach is to assess the treatment benefit incorporating a quality-adjusted life-year perspective. Patient utility, or patient preferences for their health states, report patient perceptions of

	<u>Within Trial Period</u>	<u>Post Trial Period</u>	<u>Cost</u>
<b>Deferred resource utilization</b>			
Control	Hospitalization		Hospitalization
Treatment		Hospitalization	Discounted Hospitalization
<b>Avoided resource utilization</b>			
Control	Hospitalization		Hospitalization
Treatment			No Hospitalization

**Fig. 1.** Avoided and delayed costs. The within trial period refers to events which would be observed in the period after the clinical trial. Discounted hospitalization represents the present value cost of hospitalizations which occur in the post trial period (present value reflects the time value of money; events which occur later in time are less costly than those which occur today).



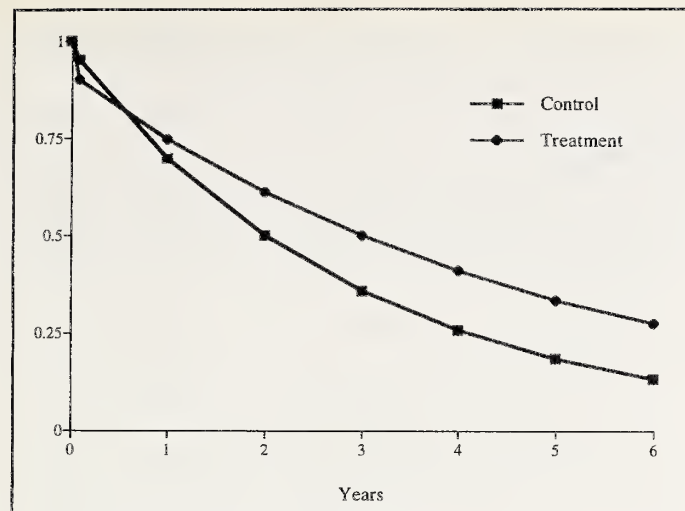


Fig. 2. Estimated survival curves for treatment and control patients. Survival curves based on 5% initial mortality and 2-year median survival in the usual-care group and 10% initial mortality and 3-year median survival in the treatment group. Probability of survival is shown on the ordinate.

the value of their current health state. By assigning patient preferences to the survival data, we can calculate the quality-adjusted life years that result for treatment and usual-care patients. As more intensive treatment regimens are considered, with

higher initial mortality rates, we can use this method to better understand and communicate the trade-off between the initial risks of treatment and subsequent treatment benefits (4) or between treatment regimens with differing side-effect profiles.

## Identification of Treatment Populations

Most bone marrow transplant studies include the use of an induction chemotherapy regimen before the patient is eligible for the high-dose chemotherapy regimen. In certain protocols, only a relatively small proportion of patients may successfully graduate from induction chemotherapy to the high-dose treatment regimen (Fig. 3). These patients are usually not included in an assessment of the effectiveness of post-induction therapies. However, for an economic evaluation, we may wish to consider the costs for treatment of all patients in the study population.

From a health care systems perspective, induction costs represent real resources that must be provided to breast cancer patients. To the extent that the success of induction regimens differs across patient populations, or treatment protocols, one might imagine that the induction costs may be a substantial proportion of the cost attributed to high-dose chemotherapy. Looking at induction costs may also improve the generalizability of the study findings. This effort would also place the eventual success of the treatment regimens into better perspec-

Table 1. Life expectancy of treatment and control patients: control median = 2 years\*

	Initial mortality rate, %	Median survival, y	Column 1†		Column 2‡	
			Unadjusted life expectancy	Discounted life expectancy	Unadjusted life expectancy	Discounted life expectancy
Control	5	2	2.94	2.50	2.94 <sup>1</sup>	2.50 <sup>1</sup>
	10	2	3.04	2.55	2.79 <sup>2</sup>	2.37 <sup>2</sup>
Treatment	10	3	4.56	3.58	4.56 <sup>3</sup>	3.58 <sup>3</sup>
	15	3	4.76	3.66	4.31 <sup>4</sup>	3.38 <sup>4</sup>
	20	3	5.04	3.78	4.06 <sup>4</sup>	3.19 <sup>4</sup>

\*Life expectancy based on exponential survival function with stated initial mortality rate and median survival for treatment and control arms.

†Data in column 1 represent results when the median survival is held constant despite the changes in the initial mortality rate.

‡Data in column 2 represent results when the conditional probability of survival is based on the survival function calculated by using the lowest initial mortality rate for each median life expectancy (superscripts 1 and 3) as initial mortality rates are increased (superscripts 2 and 4).

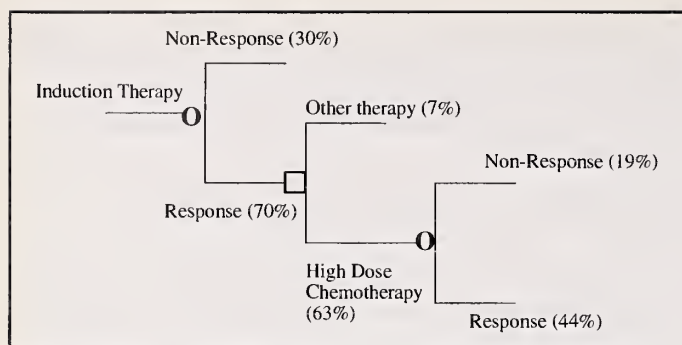
Table 2. Life expectancy of treatment and control patients: control median = 3 years\*

	Initial mortality rate, %	Median survival, y	Column 1†		Column 2‡	
			Unadjusted life expectancy	Discounted life expectancy	Unadjusted life expectancy	Discounted life expectancy
Control	5	3	4.41	3.52	4.41 <sup>1</sup>	3.52 <sup>1</sup>
	10	3	4.56	3.58	4.18 <sup>2</sup>	3.34 <sup>2</sup>
Treatment	10	4.5	6.82	4.89	6.82 <sup>3</sup>	4.89 <sup>3</sup>
	15	4.5	7.10	4.96	6.44 <sup>4</sup>	4.62 <sup>4</sup>
	20	4.5	7.49	5.07	6.07 <sup>4</sup>	4.35 <sup>4</sup>

\*Life expectancy based on exponential survival function with stated initial mortality rate and median survival for treatment and control arms.

†Data in column 1 represent results when the median survival is held constant despite the changes in the initial mortality rate.

‡Data in column 2 represent results when the conditional probability of survival is based on the survival function calculated by using the lowest initial mortality rate for each median life expectancy (superscripts 1 and 3) as initial mortality rates are increased (superscripts 2 and 4).



**Fig. 3.** Treatment populations: patients with breast cancer of stage II or IIIA. Diagram highlights the course of treatment and patient response that may be considered in an economic evaluation of high-dose chemotherapy for patients with metastatic breast cancer.

tive for health policy makers. To the extent that resources required for induction regimens are not of benefit to patients, we may wish to assess whether we can develop predictors of success of induction therapy that could be applied on a population

basis to determine which patients would be optimal candidates for induction and, potentially, treatment regimens.

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## Note

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# Proposed Phase III Trial Comparing Laparoscopic-Assisted Colectomy Versus Open Colectomy for Colon Cancer

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Despite many important medical advances, surgery remains the primary treatment modality for most of the 109 000 individuals who are newly diagnosed with colon cancer each year. Surgery not only provides extirpation of the primary tumor that relieves symptoms and prevents complications but also provides important staging information. Although oncologic results from open colectomy are well established, these traditional resective and staging techniques are challenged by the introduction of minimal-access surgery. Laparoscopic cholecystectomy, which shortens postoperative recovery and decreases disabilities and cost, has become the preferred surgical approach to cholelithiasis. Many propose that minimal-access surgery of the colon may offer similar advantages. Laparoscopic-assisted segmental resections of the colon can be performed using laparoscopic techniques to ligate vasculature and mobilize and exteriorize bowel and extracorporeal techniques to resect and anastomose bowel. Collective preliminary data from a consortium of experienced laparoscopic surgeons support that laparoscopic-assisted colectomy is safe, feasible, and reduces recovery times and disabilities. Since differences between laparoscopic-assisted and open colectomy have not been rigorously tested, and concern has been raised regarding the adequacy of this technique for staging and treating colon cancer, a prospective randomized multi-institutional trial is proposed. The primary aim of such a trial will be to test the hypothesis that disease-free survival and overall survival are equivalent, regardless of whether patients receive laparoscopic-assisted or open colectomy. The secondary aim of the trial will be to determine the safety of laparoscopic-assisted colectomy compared with open colectomy. Finally, the tertiary aim of the study will be to test the hypothesis that laparoscopic-assisted colectomy is a cost-effective alternative to open colectomy and results in superior quality of life. [Monogr Natl Cancer Inst 19:51-56, 1995]

Each year, 109 000 individuals in the United States are diagnosed with malignancy of the large intestine and approximately 50 000 die of the disease (1). Despite the introduction of important new screening and endoscopic techniques (2) and effective adjuvant chemotherapies (3), surgery remains the primary treatment modality for patients with stages I-III colon cancer. Surgical extirpation of the primary tumor relieves symptoms and prevents complications, while surgical exploration and lymphadenectomy provide staging information.

Colectomies have historically been performed using an open technique. Accepted guidelines for colectomy for cancer include thorough examination for detection of metastatic disease, minimal tumor handling to prevent tumor dissemination (4,5), proximal vascular pedicle ligation for generous sampling of lymphatics, wide bowel margins to prevent anastomotic recurrence, and en bloc resections of adherent organs to improve survival (6,7). Staging includes both macroscopic intra-abdominal examination for hepatic and peritoneal metastases, locally advanced disease, and distant nodal spread and microscopic examination of the lymphadenectomy specimen. Several serologic and radiologic tests have been introduced for purposes of colon cancer staging, especially for detection of hepatic metastases (8-10), but none are considered superior to surgical exploration. Histologic staging of the resected primary tumor and regional lymph nodes remains the standard (11-13) for both predicting recurrence and advising on adjuvant therapies (3). Oncologic results from open colectomy are well established, but are now challenged by the introduction of minimal-access surgery.

## Minimal-Access Surgery

Since its introduction in 1988, laparoscopic cholecystectomy has rapidly gained favor with patients, surgeons, and care providers such that it has become the preferred manner of cholecystectomy (14). Once surgical proficiency at laparoscopic-resective techniques advanced, indications for minimally invasive surgery expanded to include appendectomy (15), Nissen fundoplication (16), and colectomy (17). Minimal-access colon surgery includes laparoscopic procedures ranging from simple colectomy and polypectomy (18) to total abdominal colectomy and ileal pouch-anal anastomosis (19). Technical approaches range from intracorporeal procedures, where no additional incisions are required (17), to extracorporeal or laparoscopic-assisted techniques, where small abdominal incisions facilitate resection and anastomosis of the bowel outside the abdominal cavity (20). Intracorporeal colectomy that requires intracorporeal suturing has not been accepted by the surgical com-

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See "Note" section following "References."



munity because it is prohibitively difficult to perform and is associated with higher anastomotic leak rates (17).

## Laparoscopic-Assisted Colectomy

In contrast to intracorporeal laparoscopic colectomy, the extracorporeal approach of laparoscopic-assisted colectomy appears to be safe, effective, advantageous, and feasible. Based on early surgical experiences, major complications for laparoscopic-assisted colectomy range from 13% to 20% and mortality rates range from 0% to 3.6% (21-23). When operative morbidities have been compared between open and laparoscopic colectomy groups, no difference in overall morbidities [11% open versus 15% laparoscopic (21)] have been noted. Operative blood loss, another measure of surgical trauma and morbidity, was lower in laparoscopic patients (157 mL) than in converted laparoscopic colectomy patients (491 mL) or in open colectomy patients (687 mL) in one series (21). In summary, laparoscopic colectomy can be performed safely with acceptable rates of morbidity and mortality.

### Benefits

Patient-related advantages of laparoscopic-assisted colectomy, to date, have included significant reductions in time for return of bowel function and length of hospital stay. Despite the commonality of a bowel anastomosis, patients who undergo laparoscopic-assisted colectomy experience significant reductions in the length of ileus, with more rapid return of flatus (2.3 days for laparoscopic versus 3.7 days for open [ $P<.001$ ]), more rapid return of bowel movements (2.7 days for laparoscopic versus 4.0 days for open [ $P<.001$ ]), and shorter length of time until resuming oral intake (23). The reasons for this shortened length of postoperative ileus with laparoscopic surgery are not clear, but may be due to reductions in postoperative pain, narcotic requirements, bowel handling during surgery, or, finally, due to improvements in patients' sense of well being after surgery, as documented by significantly improved Karnofsky scores (21). In general, early reports suggest that postoperative recovery is faster and better tolerated in patients undergoing laparoscopic-assisted colectomy.

Despite early indications that laparoscopic-assisted colectomy offers patient-related advantages, cost benefits have not been realized as they have been for laparoscopic cholecystectomy. Costs have been analyzed in three reports comprising an evaluation of a total of 135 laparoscopic colectomy patients (21,22). When total hospital costs for all laparoscopic colectomies, completed plus converted (\$27 387), are compared with costs for open colectomies (\$24 219), the new procedure appears more expensive (24). To understand how cost is likely to change in the future, it is necessary to examine the components of cost and laparoscopic surgery. First, at least two institutions report that completed laparoscopic colectomies (\$12 131) are less costly than converted laparoscopic colectomies (\$17 583) and are, in fact, cost competitive with open colectomies (\$14 449) (21,22). Reducing conversion rates for laparoscopic colectomy will favorably influence total hospital costs for the combined group. Second, while it is evident that decreases in length of hospital stay favorably affect total cost, increases in operative time and

equipment charges increase total cost. Operating room time charges (\$4268 versus \$3061), operating room equipment charges (\$5550 versus \$2324), and anesthesia charges (\$943 versus \$640) were all significantly higher for the laparoscopic than for the open colectomy group, respectively (24). Since operative times are experience dependent and these figures are from early surgical experiences, it is likely that total costs will be reduced in the near future. Further reductions can be accomplished by the introduction of reusable equipment and reductions in conversion rates.

### Feasibility

The feasibility of laparoscopic-assisted colectomy relative to open colectomy depends on whether it can be performed in a timely fashion and with low rates of conversion. Overall operative times for laparoscopic-assisted colectomy range from 129 to 174 minutes (21,23,25). Differences in operative times for right (136 minutes) versus sigmoid (193 minutes) colectomies have been described for laparoscopic surgery (23); as would be expected, most surgeons have described shorter operative times for the open technique (21,23). Longer operative times, in part, reflect the difficulties of learning laparoscopic techniques and significant reductions can be anticipated after 10-19 cases have been performed (22-24).

Not all patients and colon lesions are suitable for laparoscopic-assisted colectomy; conversion from the laparoscopic to the open technique is required in between 14% and 41% of patients (22,23). Conversion may be necessary for any number of reasons, including technical reasons, such as the presence of prohibitive adhesions, the absence of the lesion in the specimen, instrumentation difficulties, or prolonged surgical times (22); variations in anatomy, pelvic kidney, high-splenic flexure, or unclear anatomy (22); disease-related factors, such as inflammatory adhesions or the presence of bulky or adherent tumors or abscesses (21-23); and finally, intraoperative complications, including intraoperative bleeding or bowel injuries (21-23).

Although patient selection and surgical experience with laparoscopy affects conversion rates, ideal preoperative selection criteria have not been firmly established. Surgeons who excluded patients because of obesity, multiple prior surgical procedures, or the presence of bulky disease had low conversion rates (14%) (23). In contrast, when patients with prior surgeries were included in laparoscopic series, conversions were more common and adhesions were frequently the reason for conversion (21,22). Despite these findings, no direct relationship between prior surgery and laparoscopic conversion rates was identified (22). In a series of 122 patients undergoing laparoscopic-assisted colectomy at the Mayo Clinic, patient weight greater than 90 kg was predictive of a significantly higher conversion rate (75%;  $P = .012$ ) (25). With increasing surgical experience and attention to patient selection factors, 20% conversion rates are anticipated.

### Oncologic Issues

Although, theoretically, laparoscopic-assisted colectomy offers advantages of reduced postoperative disabilities and possibly costs, it also introduces the risk that cancer outcome will be altered in patients undergoing resection for cancer cure. Neo-



plasm is a common indication for colectomy and laparoscopic colectomy for cancer has been reported (17,20,26-28). In theory, laparoscopic-assisted colectomy offers the same extent of resection and staging as open colectomy. Evidence that oncologic principles of resection are followed with laparoscopic techniques comes from lymphadenectomy and margin data. In animal models, mesenteric lymphangiography studies demonstrate that identical mesenteric lymph node resections can be performed using laparoscopic or open techniques of bowel resection (29). In patient series, lymph node sampling appears to be comparable between laparoscopic and open colectomy groups; 9.0 laparoscopic versus 8.5 open for right and 7.3 versus 4.7 for sigmoid (23); and 14 versus 9 for right and 9 versus 5 for sigmoid (22). Tumors can be laparoscopically resected with mean proximal margins of 14 cm and distal margins of 7 cm (27).

Laparoscopic-staging techniques are described for abdominal and pelvic malignancies (30-33), but the accuracy of laparoscopic staging for colon cancer is not known. Intra-abdominal inspection for detection of peritoneal disease, advanced local disease, and proximal lymph node sampling (31) is likely possible, but palpation for hepatic metastases is not feasible at this time. Abdominal computed tomography scans, with a negative predictive value of 90% (9) and sensitivity of 100% compared with surgery (10), may resolve the limitation of laparoscopic liver assessment. Even though laparoscopic-assisted colectomy seems to offer the same cancer operation, important differences in cancer outcome may not yet have been appreciated.

An additional oncologic issue regards the potential risk of tumor contamination of the wound. Wound and trocar recurrences have been described for both laparoscopic cholecystectomy (seven cases) and colectomy (four cases) (34-42), but the incidence is unknown and therefore cannot be directly compared with the 1% incidence described for patients undergoing curative resection of colorectal cancer using celiotomy (43). It is presumed that exfoliated viable tumor cells implant in wounds where healing properties provide optimal growth conditions (44-46). Spillage and direct tumor handling during surgery may exacerbate this problem, but direct tumor handling is not a prerequisite (39).

That laparoscopic-assisted colectomy may provide an oncologic advantage has not been addressed. Laparoscopic-assisted colectomy may positively influence cancer outcome by decreasing surgical trauma, stress, postoperative disabilities, and postoperative recovery periods, thereby allowing improved compliance with, and earlier administration of, adjuvant therapies. Evidence that surgical stress is lessened after laparoscopic colectomy comes from studies of serum cortisol and interleukin 6 levels, both of which rise proportionate to the degree of surgical trauma (47). Finally, evidence that administration of chemotherapy in the early postoperative period may provide benefit comes from early evaluations of levamisole (48). A trial is necessary to determine the clinical significance of the potential advantages and disadvantages.

## Prospective Randomized Trial

To establish the true risks and benefits of laparoscopic-assisted colectomy, a prospective randomized trial is proposed.

The primary aim of such a trial will be to test the hypothesis that disease-free survival and overall survival are equivalent, regardless of whether patients receive laparoscopic-assisted or open colectomy. The secondary aim will be to determine the safety of laparoscopic-assisted colectomy compared with open colectomy, including early and late morbidities and operative mortality. The tertiary aim will be to test the hypothesis that laparoscopic-assisted colectomy is a cost-effective alternative to open colectomy and provides superior quality of life. Measurable end points for quality of life include patient self-reported symptoms, functional status, utilities, and early and late surgical complications. Measurable end points for cost include resource utilization at all participating institutions and actual costs at three select institutions.

Twelve-hundred patients with the diagnosis of a single adenocarcinoma of the right, left, or sigmoid colon will be randomly assigned to receive a laparoscopic-assisted or open colectomy over a 3-year accrual period. Patients will not be eligible if they are pregnant or have prohibitive scars or adhesions, advanced local or stage IV disease, rectal cancer, transverse colon cancer for technical reasons, acutely obstructed or perforated cancer, associated gastrointestinal disease, or other malignancies. Patients will be stratified by tumor site, primary surgeon, and risk of surgery and anesthesia according to the American Society of Anesthesiology classification. To ensure an efficient, successful, high-quality study, an intergroup mechanism will be used to conduct the study. Participating surgeons have experience with the technique of laparoscopic-assisted colectomy and have agreed to perform resections according to uniform guidelines. For quality-assurance purposes, random audits of video-recorded laparoscopic procedures will be performed during the trial.

## Analyses of Recurrence and Survival

Patients will be followed for 8 years in a standard fashion for cancer recurrence and survival. The primary end point for initial reporting of study results will be recurrence. The plan is to perform the first analysis with a logrank statistic when 437 patients have recurred. If the one-sided *P* value is  $<.09$  in favor of the open colectomy, it will be concluded that the open colectomy is still the surgery of choice. Otherwise, it will be concluded that the recurrence rate is not significantly worse for the laparoscopic-assisted colectomy and additional cost and quality-of-life analyses will be performed. All eligible patients will be included in the analysis according to the assigned surgical procedure (intent to treat). Calculations of power are based on two assumptions. It is first assumed that there will be nearly equal distribution of patients between high-risk Dukes' B2 and C stage (67% 3-year recurrence-free survival rate) and Dukes' A and B stage (93% 3-year recurrence-free survival rate). It is secondly assumed that one fifth of the patients assigned to the laparoscopic-assisted colectomy group will fail to receive it and, therefore, will provide no useful information. Based on these assumptions and the fact that there are two interim analyses, there is a 10% chance that the two treatments are equivalent, but it will be erroneously concluded that laparoscopic-assisted colectomy increases the risk of recurrence. There is a 9% probability



of concluding equivalence when there is a true or absolute 6% decrease in the 3-year recurrence-free rate for laparoscopic-assisted colectomy; this probability rate drops to 0.2% when there is a 10% absolute decrease in 3-year recurrence-free rate for laparoscopic-assisted colectomy. A second major analysis for survival will be performed when all patients have been followed for 7 years.

## Quality of Life

Early morbidities and mortality will be monitored in the immediate postoperative period and 2 months postoperative. Late and delayed major morbidities, such as bowel obstruction, will be monitored by tracking intervening hospitalizations. Details of hospital admissions, dates, location, and admitting physician's name will facilitate direct confirmations as to whether the hospitalization was related to the cancer diagnosis and surgery or for other reasons. Late and delayed minor morbidities that were managed on an outpatient basis will be monitored by inquiries regarding "nonroutine" clinic or outpatient visits or phoned prescriptions. Patient self-reported symptoms, functional status, and utilities will be assessed at the time of study entry, in the early postoperative period, and at 2 and 18 months after surgery. Symptoms will be assessed using the McCorkle Symptom Distress Scale (49,50). Functional status and utilities will be elicited with the quality-of-life index and a 0-100 rating scale of overall quality of life (51,52). Comparisons between arms at 14 days, 2 months, and 18 months will be performed with repeated measures of analysis of variance.

## Quality-Adjusted Survival Analysis

Quality-adjusted survival will be calculated using the method of Q-TWiST (quality-adjusted time without symptoms of disease and toxicity of treatment) (53), which integrates quality-of-life considerations into the comparison of treatments. The Q-TWiST method proceeds in four steps. First, health states likely to be characterized by different levels of quality of life are identified for the specific disease under study and the treatments being evaluated. Second, overall survival time of patients in the study is partitioned into these health states. Third, the total time spent in each health state by patients in each arm of the trial is multiplied by a utility coefficient or weight reflecting the quality of life reported by patients in that health state. Finally, the average quality-adjusted survival in each trial arm is determined by summing the weighted survival times. Five health states will be included in the Q-TWiST analysis (53,54): the perioperative period, adjuvant chemotherapy, TWiST (time without symptoms and toxicity), late complications, and relapse.

The duration of the perioperative period will be defined as the first 30 postoperative days. The duration of the adjuvant chemotherapy period will be measured from the date of first chemotherapy until 30 days after the last dose of chemotherapy. TWiST will be defined as the time from the end of the perioperative period to recurrence or study closure, whichever occurs first, less the duration of adjuvant chemotherapy. Late complications will be identified through follow-up. Any complications resulting in hospitalization will arbitrarily be assigned

a duration of 1 month. Relapse will include time from the diagnosis of recurrence to death or study closure.

Utility weights will be calculated separately for each arm of the trial and will be obtained directly from trial patients. Q-TWiST quality-adjusted survival for each treatment group will be calculated by multiplying time spent by trial patients in each health state by the mean patient-reported utility for that state according to the following formula:

$$\text{Q-TWiST} = u_{\text{periop}} \times 30d + u_{\text{chemo}} \times \text{duration}_{\text{chemo}} + u_{\text{TWiST}} \times \text{duration}_{\text{TWiST}} + u_{\text{comp}} \times \text{duration}_{\text{comp}} + u_{\text{rel}} \times \text{duration}_{\text{rel}}$$

The data will also be presented graphically for each treatment arm as shown in the hypothetical plot in Fig. 1. Quality-adjusted survival is the area under the overall survival curve with each labeled health state region weighted by a utility weight reflecting the quality of life experienced by trial patients in that health state. As illustrated in Fig. 1, even if the Kaplan-Meier curves of overall survival and disease-free survival are identical in the two groups, the quality-adjusted survival may be different if patient-reported quality of life for one or more health states is different or if patients in one arm experience more complications or differ in the average length of time receiving chemotherapy. The calculation of quality-adjusted survival using the Q-TWiST method allows these differences to be summarized in a single measure and to be used to determine the cost-effectiveness of one treatment compared with the other.

## Cost Analysis

Cost analysis will be based on a comparison of differences in the costs and resources used in caring for patients receiving laparoscopic-assisted versus open colectomy. In other words,

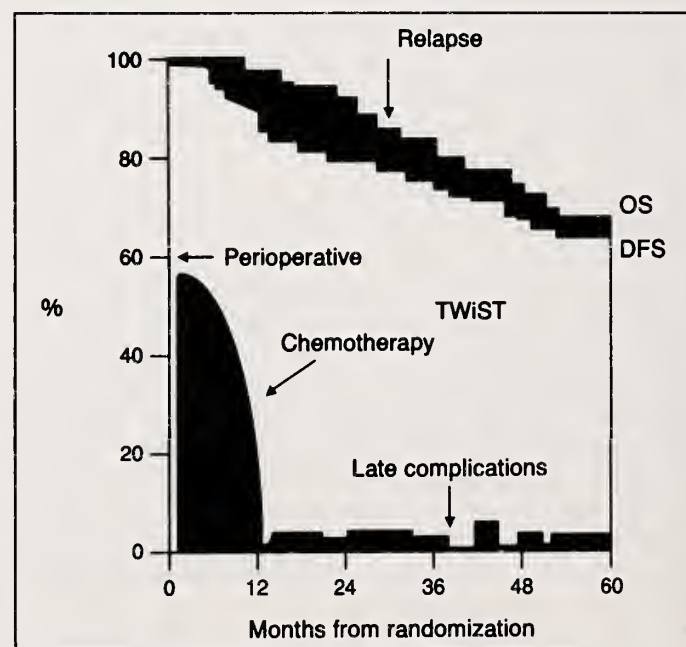


Fig. 1. Q-TWiST (quality-adjusted time without symptoms of disease and toxicity of treatment). Quality-adjusted survival is the area under the overall survival (OS) curve with each labeled health state region weighted by a utility weight reflecting the quality of life experienced by trial patients in that health state.



the analysis will generate an estimate of the marginal cost of performing the more expensive procedure rather than an estimate of the total cost of each therapeutic strategy. Consequently, the analysis will focus on the costs incurred in the perioperative period, when resource use is most likely to be different in the two arms. Later differences in costs between the two patient groups could arise if the treatments prove to result in different rates of recurrence or death. However, if there are statistically significant differences in these outcomes between groups, differences in cost are of little interest. Consequently, cost data related to recurrence will not be collected. Differences between treatment arms in the rate of late complications, however, would not obviate an economic analysis. Therefore, costs and resource use for any complications that result in hospitalization will be collected.

The analysis will focus on the collection of resource-use data so that the results will be generalizable to all clinical centers. Reporting of resource use will permit a calculation of the estimated difference in cost between the two treatment strategies to be performed for any set of input costs. For example, a nontrial center in an area with unusually high wages but unusually low supply costs will be able to estimate the expected cost consequences of adopting laparoscopic-assisted colectomy in their institution, even if their input costs or charge structure differ from those in the study centers. Resources included in the analysis will be number of hospital days (for the primary surgery as well as any subsequent treatment-related complications), number of intensive care unit days, operating time, anesthesia time, and laparoscopic supplies consumed. Previous analyses identified these as resources that differed most between treatments (21-24).

Detailed data on charges incurred by study patients will be collected at three diverse study sites, which vary in size, geographic location, and academic affiliation, including one center that has already published results of a cost analysis on 140 patients (21). These data will be used to generate an estimate of the mean charge for each resource unit consumed by patients in each treatment arm. Costs will be estimated from charges through the application of hospital-specific departmental ratios of costs to charges.

Observed rates of resource use in all trial patients will be multiplied by these category-specific costs to estimate the difference in costs between the two treatment strategies. To assess the accuracy of these cost estimates, they will be compared with estimates derived from application of the chart-based formula for calculating imputed charges developed by Kukull et al. (55).

## Cost-Effectiveness Analysis

A comparison of the costs of the alternative procedures will be undertaken only if no differences are found in cancer outcomes between the groups. This analysis will be done in two ways. First, using a cost-minimization approach in which the two procedures are assumed to provide equal benefit, the marginal cost of the more expensive procedure will be calculated. Second, to determine whether the excess cost of the more expensive treatment is justified by superior outcomes, a cost-effectiveness analysis will be performed. In this analysis, the

incremental cost of that procedure will be divided by its incremental benefit measured in quality-adjusted survival derived from the Q-TWiST analysis. Since this is an equivalence trial with respect to survival, any difference in quality-adjusted survival between treatment groups will be due to superior quality-of-life outcomes in one arm. If the less expensive procedure results in superior or equivalent quality-adjusted survival, it will be declared superior. Otherwise, the cost-effectiveness ratio will be calculated and compared with generally accepted norms. A ratio greater than \$100 000 per quality-adjusted year of life produced will be considered cost-ineffective, and a ratio less than \$35 000 per quality-adjusted year of life produced will be considered definitely cost-effective.

## Conclusion

Early reports suggest that laparoscopic-assisted colectomy is safe, feasible, and may offer important patient-related benefits. The role of laparoscopic-assisted colectomy in the management of curative colon cancer has not been established, and a prospective randomized trial is therefore proposed. The primary objective of this trial will be to determine if laparoscopic-assisted colectomy offers the same chance for cure as open colectomy. Further objectives will include comparative evaluations of safety, quality of life, and cost-effectiveness.

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# Clinical and Economic Assessment of New Surgical Technologies

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Although medical innovation can reduce morbidity and mortality associated with diseases or their treatments, in most instances new interventions tend to increase the amount of resources expended on health care services. In this era of increasing cost consciousness, there is a perceived tension between the desire to improve health outcomes and the necessity to control the growth of health care costs. The dramatic changes in the organization, financing, and delivery of health care services make it no longer acceptable to provide any and all services to every individual with only a remote probability of clinical benefit. An incentive structure that rewards the practice of cost-effective medical care is rapidly replacing the "technological imperative" of decades past.

Innovation in the field of surgery is occurring at a breakneck pace. Since evidence demonstrating the effectiveness of operative procedures is frequently unavailable prior to their adoption by surgeons, evaluation of the impact on clinical, economic, and social outcomes becomes an expensive and methodologically formidable task. However, the challenges confronted by health care technology assessors are not viewed as insurmountable. What appears to be certain is that the status quo—decision making in a data-free environment—is no longer viewed as acceptable by patients and payers.

As the outcomes movement takes hold in medical care, accountability for our actions takes paramount importance. The tradeoffs between technologic innovation and a greater emphasis on effectiveness measures need to be carefully investigated. Accordingly, the objectives of this article are to provide some background discussion of the important issues relating to the evaluation of medical innovation and the adoption of new surgical procedures. As the importance of cost-related outcomes begins to rival the traditional outcomes of safety and medical effectiveness, an introduction to economic evaluative methods is included. These methods are described in greater detail elsewhere in this monograph (Introduction by Schulman).

## Evaluation of Medical Care

Substantial evidence indicates that American physicians are receptive to innovation. Each year, one in three American practitioners adopts at least one new intervention from the thousands of new diagnostic tests, drugs, and devices offered by health care manufacturers (1). The use of each of these innovative technologies is accompanied by the prospect of enhanced clinical benefits and resultant improvements in health-related quality of life. Until recently, the urge to offer anything and everything possible for a patient, regardless of resources expended, was a major influence on physicians' tendency to adopt emerging

technology (2). This may explain why roughly only 20% of interventions used in clinical practice have been demonstrated to be effective by rigorous scientific evaluation.

In the current cost-conscious health care environment, decisions to adopt medical innovation can no longer be made exclusively on the basis of efficacy, "Does it work?"—but must incorporate the concept of efficiency, or "What are we getting for our money?" into the process. Ideally, these decisions to adopt new technology would be data driven, based on research addressing outcomes important to patients, providers, payers, and society. With efficiency embodied in the decision-making process, relatively beneficial interventions would be rapidly adopted, those judged to provide fewer benefits relative to their costs constrained, and diffusion of harmful technologies impeded.

In the absence of a formal mandate, such as the Food and Drug Administration's (FDA) requiring of evidence establishing safety and efficacy for pharmaceuticals, medical innovation regularly diffuses into medical practice without available information of its impact on patient outcomes. As a result, history provides us with examples of ineffective or even dangerous interventions that were widely adopted in medical practice (e.g., internal mammary ligation for coronary artery disease, optic nerve decompression for ischemic optic neuropathy, and gastric freezing for peptic ulcer disease) (3,4). In some instances, these shortcomings and potential hazards were made known to the public through the publication of controlled clinical studies, while others were brought to attention through epidemiologic investigations and even more through postmarketing surveillance studies.

As clinical practice patterns conform to the cost-containment objectives put forth by managed competition and move away from behavior consistent with fee-for-service payment schemes, assessment of medical innovation on clinical and economic grounds prior to regulatory approval or payer reimbursement may soon become the norm. There is little disagreement that there is much room for improvement in the way we assess risks, benefits, and cost of medical care interventions (5). However, deciding how best to perform assessments of medical technologies that meet the objectives of the multiple interests concerned about the delivery of health care services (patient, provider, payer, and society) is an ambitious undertaking.

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Moreover, the movement toward increased evaluation is not without limitations.

It is implicitly understood that striking a balance between increased regulation and ensuring the continued stream of innovation is one of the defining goals of public policy (6). To offset the potential negative effects of enhanced data collection requirements on the flow of technologic advances, efforts are being made to minimize the amount of time and resources necessary to perform assessments. Less stringent entry criteria for clinical trials allow broader patient enrollment (e.g., women, elderly) to increase the generalizability of the findings to everyday practice. Data requirements are being simplified in an attempt to reduce costs and encourage participation by community-based practitioners. These protocol adjustments should make evaluative efforts more acceptable to nonacademic providers and payers of care. However, these improvements do not come without a cost; the desire to minimize data collection will limit the richness of the analyses, particularly in those areas with intensive data requirements, such as patient preferences.

Financial support for evaluative research has become a matter of intense debate. As clinical medicine moves toward the concept of a market economy, a tension has developed between manufacturers and payers over financial responsibility for this immense task. Pharmaceutical manufacturers have invested heavily in this area, which may be a response to an individual company's need to demonstrate the superiority of a specific product within a class of drugs. Biotech companies and device manufacturers appear to be slowly following suit as payers begin to ask for outcomes in addition to improved health benefits (e.g., cost, quality of life) on which to base reimbursement decisions.

Funding sources for innovations, such as the venture capital industry, are becoming increasingly apprehensive of the risk and cost involved with an investigational new device or drug. This point may be illustrated by the rarity of breakthrough products receiving approval by the FDA; instead, a preponderance of me-too drugs and devices are being developed to compete in previously identified markets with significantly lower financial risk. In addition to the concerns about profitability and limitations on patent life, expense and practicality are responsible for the paucity of controlled experiments in most clinical areas.

Improved health remains the primary driving force for the development of medical innovations—but now may no longer be enough. As we move into an era of managed competition and self-contained delivery systems, other non-health-related factors, such as profit, prestige, and competitiveness in the recruitment of patients and staff, play a significant role in the decision to adopt a new intervention. Until very recently, coverage decisions and generous reimbursements by third-party insurers were established without documentation of effectiveness, lubricating the pipeline for a continuous stream of innovation (6,7). As payers begin to pay more attention to issues of effectiveness and cost-effectiveness of medical interventions, incentives for developers are moving from clinical benefit at any price to one of clinical benefit at what cost?

Under the old cost-based reimbursement system, new products had to demonstrate a measurable clinical benefit and incremental cost increases were of no importance. Under man-

aged care, a new product may be marketed on the promise to produce equivalent health benefits at lower costs. This widely accepted phenomenon in consumer goods—competition on price as well as quality—was irrelevant to the medical care sector until concern about health care costs became a national issue.

From the payer perspective, since valid and reliable outcome data on the safety, efficacy, and cost-effectiveness of many new interventions are not available, adoption decisions are made regularly with the reliance on imperfect or nonexistent effectiveness data (7). The end result has been an inconsistent pattern of adoption and use that has led to the underutilization of effective technologies (e.g., immunizations, thrombolytic therapy for acute myocardial infarction) and widespread use of unproven technologies (e.g., home fetal monitoring). In an effort to respond to these concerns and today's intensely competitive health care environment, technology assessment and effectiveness research activities have become priorities of nearly every large managed care firm.

## **Surgical Innovation: the Laparoscopic Revolution**

Since the advent of laparoscopic cholecystectomy in the late 1980s, all surgical specialties are undergoing a major facelift. In a matter of a few years, scores of open procedures—some performed in the same fashion for nearly a century—have been transformed into an endoscopically guided version (8). Some of the more prevalent minimally invasive procedures are as follows: cholecystectomy, hysterectomy, appendectomy, lung resection, herniorrhaphy, peptic ulcer surgery, lysis of adhesions, and splenectomy. In slight contrast to a majority of medical innovations that claim an improved clinical result, endoscopic surgery presupposes equivalent outcomes in terms of the surgical result in most instances but offers a technically superior method of achieving the same operative outcome. Thus, the benefits of these minimally invasive techniques tend to be process related and are linked to patient preferences or resource use, not to the surgical result. The advantages of the less invasive method include: less pain, shorter hospital stay, more rapid return to base-line activity, and improved cosmetic result.

Assertions of lower resource use for laparoscopic procedures have been put forth but have not yet been substantiated for most operations. Even if per case cost reductions occur, these data must be put into perspective. One must pay careful attention to any behavioral response that may occur in response to the use of new procedures. The resultant changes in volume of services are crucial in the evaluation of the overall economic impact. Changes in use can potentially outweigh even substantial reductions in unit costs. If the innovative procedure is deemed as better, then one naturally expects an increase in its use. The early experience with laparoscopic cholecystectomy exemplifies this point—a 40% reduction in cost per procedure was more than eliminated by an unexpected 60% increase in overall cholecystectomy volume (9). Thus, the total resources being devoted to gallbladder disease have increased significantly in the laparoscopic era. Similar data on other laparoscopic procedures are not yet available.

The dynamics behind the widespread adoption and use of endoscopic surgery are complicated and have been described else-



where (10). A number of interrelated factors that have contributed to this phenomenon are as follows: technological capacity, surgeons' acceptance of potential advantages, changing hospital reimbursement, patient demand, manufacturers' marketing, and payers' desire to decrease expenditures. Critics of prospective outcomes assessment argue that if effectiveness or cost-effectiveness evaluations had been mandated onto the device industry in 1988, laparoscopic cholecystectomy may not have passed muster. Surgeon experience and the refinement of devices and operative technique have led to the eventual maturation of this procedure to its current state.

Interestingly, laparoscopic cholecystectomy became the most rapidly diffusing surgical procedure without a single controlled evaluation documenting either safety or efficacy (11). As laparoscopic cholecystectomy became more mainstream, applications and indications for endoscopic surgery followed suit. Procedures expanded from the more straightforward identification and removal of the affected organ (gallbladder, appendix, and uterus) to operations that involved delicate dissections and organ repair (8). More slowly, it has moved into procedures with outcomes that extend far beyond the perioperative period—similar to those for malignant disease, e.g., colorectal cancer.

Evaluating Surgery

Methods used in health care technology assessments differ in terms of validity, reliability, and rigor; studies vary in terms of populations examined, sample size, and study site. Except when mandated by a regulatory authority (i.e., FDA), the randomized controlled trial is performed infrequently. Some of the challenges that arise in the assessment of surgical procedures are as follows: surgery is a process, not an outcome; inter- and intra-surgeon variation; learning-curve phenomena; surgeon/patient biases; and outcomes of interest often are in the distant future. Regardless of the source and rigor of the information available, limitations exist regarding the usefulness of the resultant outcome data. Two of the more noteworthy limitations are timing of assessment and providers' concerns that patients in the research studies are not similar to those seen in everyday practice.

Because of the rapid evolution of medical innovations, sometimes described as the moving target phenomenon, changes in benefit and cost parameters make the timing of evaluative efforts a challenge. Moreover, there are difficulties generalizing assessments of efficacy (measured under optimal conditions) to effectiveness (measured under usual conditions).

A randomized trial of laparoscopic-assisted colectomy versus open colectomy is of significant interest in that it allows prospective assessment of a number of important outcomes from multiple points of view (Table 1). The primary goal of this investigation is to demonstrate whether laparoscopic colectomy is a similar operation in terms of colon cancer survival and operative safety when compared with its open counterpart. If equivalent in these measures, secondary comparisons of patient preferences and economic outcomes between the two interventions would also be prospectively evaluated.

Economic Evaluation

Cost Identification or Cost Minimization Analyses

When the outcome of interest of two interventions is truly equivalent, a special type of economic analysis called "Cost Identification or Cost Minimization Analysis" may be used (12). This method makes a central implicit assumption that outcomes of study interventions are equal. The goal then is to determine the least expensive way of achieving that outcome. Since no detailed health outcome data are necessary, cost incurred of disease and/or services used to treat that disease are calculated and usually presented as dollars per case.

Cost-Effectiveness Analyses

In the rare instance when a new intervention both improves health and lowers cost (e.g., immunizations), a dominant scenario arises and leaves no discussion regarding adoption policy. However, in most circumstances in clinical medicine, additional resources are devoted to achieve a preferred clinical outcome. Because equivalence in outcomes of interest are rarely achieved, cost-effectiveness analysis, a method that incorporates both clinical benefits and resource use, is required. This method has been discussed in great detail earlier in these proceedings (Introduction by Schulman). Cost-effectiveness analysis allows us to quantify the cost, which may be measured as currency (e.g., dollars, pounds) or other resource units (e.g., bed days), to achieve an incremental benefit among alternative interventions.

Policy Implications

The research/policy interface is identified when interventions are recognized that bring about improved health outcomes at incremental expense (or worse health outcomes at lower cost). For informed decisions to be made, similar data need to be available

Table 1. Assessment of surgical procedures: outcomes of interest

Surgical outcomes
Extent of resection/staging
Surgical margins
Lymph node exploration
Perioperative issues
Narcotic requirement
Return of bowel function
Complications
Long-term issues
Patterns of recurrence
Rehospitalizations
Patient health status: quality of life
Perioperative
Complications
Adjuvant therapy
Remission
Relapse
Resource use
Locus of care: inpatient or outpatient
Length of stay
Intensity of resources; ICU days
Equipment requirements
Indirect costs: work loss, home needs
Intangible costs: pain and suffering

for alternative options on which to spend health care resources. To meet this goal, a more concerted effort to collect clinical and economic data to better assess surgical interventions is warranted.

Improvements in the tools designed to measure health-related quality of life and the cost impact of medical innovation should enhance these assessments and lead to their greater acceptance in the medical marketplace.

Unfortunately, the financial responsibility for the conduct of effectiveness research remains a matter for debate. Regardless of who pays, the value of medical interventions must be determined to enable health policy makers to better allocate our scarce health care resources.

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# Phase III Trial (E5592) Comparing Cisplatin Plus Etoposide With Cisplatin Plus Paclitaxel at Two Dose Levels for Treatment of Advanced Non-Small-Cell Lung Cancer

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*For the Eastern Cooperative Oncology Group*

Non-small-cell lung cancer (NSCLC) is the most common cause of cancer-related death in the United States. Only about 30% of patients present with surgically resectable (and thus curable) disease. Because existing chemotherapeutic regimens are never curative in advanced NSCLC and because the median survival time is only modestly increased, the Eastern Cooperative Oncology Group (ECOG) has concentrated on a broad phase II testing program designed to identify new agents with activity against the disease. Of the more than one dozen drugs that have been thus evaluated during the past 10 years, only paclitaxel (Taxol) has been shown to result in an objective response rate of more than 20%. To determine if the paclitaxel-containing regimen can increase survival, ECOG has, therefore, embarked on a phase III trial (E5592) in which patients with stage IV NSCLC are randomly assigned to receive either cisplatin plus etoposide (the current standard chemotherapy) or cisplatin plus paclitaxel. The trial design should also help to determine the appropriate dose of paclitaxel in this clinical setting. [Monogr Natl Cancer Inst 19:61-63, 1995]

Non-small-cell lung cancer (NSCLC), the second most commonly diagnosed cancer in the United States, is the most common cause of cancer-related death in the United States. NSCLC constitutes one out of every three cancer deaths in men and one out of every five cancer deaths in women. The 5-year survival rate for patients with NSCLC is only about 13%, a figure that has remained relatively constant over the last 20-30 years (1).

Only about one third of patients present with disease that can be surgically removed. The majority of patients have either clinically obvious distant metastases (stage IV disease) or locally advanced disease that is almost always unresectable (stage IIIB and most of stage IIIA disease) (1). For these latter groups of patients with more advanced disease, some form of systemic therapy is needed if the 5-year survival rate of 13% is to be improved.

The principal goals of chemotherapy in general are to 1) cure the cancer, 2) prolong survival, and 3) provide palliation of

tumor-related symptoms. Unfortunately, in NSCLC, chemotherapy is not curative in the presence of clinically obvious metastatic disease. Relatively few chemotherapeutic agents have shown "activity" in NSCLC. Activity is defined here as resulting in an overall response rate of at least 15%. Drugs that have shown such activity as single agents include cisplatin, ifosfamide, mitomycin, vinblastine, and vindesine (2). More recently, several new agents have yielded relatively high levels of activity; they include paclitaxel (Taxol) (3), docetaxel (4), CPT-11 (5), gemcitabine (6), and vinorelbine (7).

There has been a question about the role of combination chemotherapy in NSCLC. Combination chemotherapy can achieve much higher overall response rates, compared with response rates achieved with single agents. But does that translate into a real benefit to the patient in terms of prolonging survival? In general, chemotherapy in NSCLC may modestly improve the median survival rate for patients with stage IV disease (8,9), may provide palliation in stages III/IV disease (10), and may be useful in conjunction with thoracic radiotherapy (11); the role of chemotherapy, if any, in the preoperative setting, however, remains undefined.

The ability of existing chemotherapy regimens to extend survival has been the subject of several randomized trials in which chemotherapy was compared with best supportive care (8,9). In most of these studies, best supportive care consists of pain medication, antibiotics, steroids for hypercalcemia or increased intracranial pressure, and irradiation for painful, bony metastases or to relieve bronchial obstruction; the chemotherapy employed is usually cisplatin based. Patients managed with supportive care live an average of 13-17 weeks compared with 20-30 weeks for patients receiving chemotherapy. The improvement in the median survival time, 7-14 weeks, is essentially equivalent to the time spent receiving chemotherapy, resulting in some

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controversy as to the true benefit of chemotherapy in this setting (8,9).

None of the randomized studies done to date have adequately addressed the palliative benefits of chemotherapy. In nonrandomized trials, however, chemotherapy has been shown to diminish the incidence of tumor-related symptoms, including cough, dyspnea, and chest pain, in up to 75% of patients (10,12).

Because existing chemotherapy regimens are never curative in patients with stage IV NSCLC and because the median survival time is only modestly increased, the Eastern Cooperative Oncology Group (ECOG) has concentrated its resources into a broad phase II testing program designed to identify new agents with activity against NSCLC. During the past 10 years, nearly a dozen agents have been evaluated (Table 1). Only paclitaxel has produced an objective response rate greater than 20%, the criterion established as indicative of activity. Forty percent of the patients entered into the ECOG trial were still alive at 1 year (3). In all previous ECOG trials, regardless of whether patients received single-agent or combination chemotherapy, the 1-year survival rate rarely exceeded 20% (13). Virtually identical response and survival results were obtained in a phase II trial of similar design carried out by The University of Texas M. D. Anderson Cancer Center, Houston (4). Taken together, the results of these two trials indicate that paclitaxel is an agent worthy of further study for the treatment of NSCLC.

### Phase III Trial

On the basis of the phase II experience, ECOG investigators designed a phase III trial (E5592) in which patients with NSCLC of stage IV are randomly assigned to receive either cisplatin plus etoposide or cisplatin plus paclitaxel. Paclitaxel is given at either a low dose (135 mg/m<sup>2</sup>) or a high dose (250 mg/m<sup>2</sup>). Patients receiving high-dose paclitaxel also receive granulocyte colony-stimulating factor (G-CSF) (Fig. 1).

The rationale for this trial is as follows: (a) Cisplatin and paclitaxel both possess activity against NSCLC. (b) Paclitaxel and cisplatin have demonstrated additive cytotoxicity in preclinical studies. (c) A phase I trial conducted at the Johns Hopkins Oncology Center demonstrated the feasibility of administering combined paclitaxel (135 mg/m<sup>2</sup>) and cisplatin (75 mg/m<sup>2</sup>) without G-CSF (14). (d) Another phase I trial at the

**Table 1.** Phase II agents used in treatment of NSCLC—10-year experience of ECOG\*

Agent	Response†	%
Carboplatin	8/88	9
Iproplatin	5/88	6
Acivicin	0/42	0
Echinomycin	2/41	5
Trimetrexate	2/40	5
Teniposide	0/15	0
Gallium nitrate	0/13	0
Amonafide	0/18	0
Merbarone	1/39	3
Piroxantrone	1/44	2
Paclitaxel	5/24	21

\*Modified from Chang et al. (3,13).

†Values = number of patients responding/total number of patients treated.

Johns Hopkins Oncology Center demonstrated the feasibility of administering high-dose paclitaxel (250 mg/m<sup>2</sup>) and cisplatin (75 mg/m<sup>2</sup>) in combination, provided that G-CSF was used to minimize myelosuppression (15). (e) The optimal dose of paclitaxel for the treatment of NSCLC is unknown. Objective responses in patients with NSCLC have been documented with both low-dose (110 mg/m<sup>2</sup>) and high-dose (250 mg/m<sup>2</sup>) levels.

### Trial Objectives

This trial seeks to determine if cisplatin plus paclitaxel will increase the survival of patients with stage IV NSCLC compared with patients given a "standard" chemotherapy regimen (cisplatin plus etoposide). The trial design also should help determine the appropriate dose of paclitaxel for treatment of patients with NSCLC. In addition to yielding the highest 1-year survival rate among stage IV NSCLC patients entered into previous ECOG trials, cisplatin plus etoposide is a well-tolerated regimen commonly used in the community setting and is, therefore, a reasonable standard treatment. The median survival time observed with cisplatin plus etoposide in patients with stage IV disease is about 20-25 weeks, and the 1-year survival rate is about 20%. Life-threatening toxic effects are relatively uncommon and generally consist of myelosuppression. (Grade 3 or 4

#### Stratification:

Performance Status 0 vs 1  
Weight Loss in Previous 6 Months <5% vs >5%  
Disease Stage IIIB vs IV  
Disease Measurability: Bi-dimensional measurable vs. Evaluable Disease

R	---	ARM A	Cisplatin, 75 mg/m <sup>2</sup> IV over 1 hour. Day 1
A			VP-16, 100 mg/m <sup>2</sup> /Day IV over 45 minutes. Days 1, 2, and 3
M			
D	---	ARM B	Taxol, 250 mg/m <sup>2</sup> IV over 24 hours. Day 1
O			Cisplatin, 75 mg/m <sup>2</sup> IV over one hour. Day 2
M			G-CSF, 5 ug/kg/day SC beginning Day 3
I			
Z	---	ARM C	Taxol, 135 mg/m <sup>2</sup> IV over 24 hours. Day 1
E			Cisplatin, 75 mg/m <sup>2</sup> IV over one hour. Day 2

**Fig. 1.** Schema for phase III trial (E5592). All treatment courses will be repeated every 21 days. The ECOG performance status was used. Taxol = paclitaxel; VP-16 = etoposide; IV = intravenous; SC = subcutaneous.



myelosuppression is 40%-50% [Common Toxicity Criteria, Cancer Therapy Evaluation Program, Division of Cancer Treatment, National Cancer Institute].) Paclitaxel at a high dose of 200-250 mg/m<sup>2</sup> yielded a median survival time of 40 weeks in the M. D. Anderson phase II trial and a 1-year survival rate of more than 40% in both the ECOG and M. D. Anderson trials.

Grade 3 or 4 myelosuppression proved to be the principal toxicity in the phase II trials and was observed in more than 65% of the patients. The main toxicity of paclitaxel plus cisplatin was myelosuppression at the lower dose (grade 3 or 4 myelosuppression of >80%) and neurotoxicity at the higher dose. However, even with the addition of G-CSF, myelosuppression remained a significant problem; more than 70% of the patients experienced grade 3 or 4 leukopenia. Therefore, in addition to survival comparisons, a comparison of toxic effects will be made between the three arms.

In addition to comparing survival and toxicity, the E5592 trial seeks to determine the quality of life of all patients by using the "FACT-L," an instrument developed by ECOG investigators for this purpose (16).

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# Potential Evaluation of the Incremental Cost-Effectiveness of Paclitaxel in Advanced Non-Small-Cell Lung Cancer (Eastern Cooperative Oncology Group 5592)

Bruce E. Hillner\*

The number of published studies of economic evaluations of health care services has grown exponentially over the last decade. Only a handful have addressed oncology issues. Oncologists have concentrated on the following question: "Does the treatment cause a response?" Given the combination of shrinking resources, an aging population, and growth in innovative biotechnologic approaches that are generally expensive, clinical oncology has belatedly joined the health care debate that choices between alternative uses of health care resources are necessary.

The most direct approach to controlling the adoption and use of a new technology is to assess the economics prior to dissemination. Over the last 30 years, there has been a recurring pattern of technologies that rapidly diffuse into common use without systematic comparison to current technology, e.g., radiologic imaging, coronary bypass grafting, and high-dose chemotherapy for solid tumors. If an economic assessment is done at an early stage, few political positions and academic reputations are threatened. It is almost universally easier to avoid initiating a service than to discontinue it later. Given its strong commitment to clinical research and randomized trials, the oncology community should be receptive to parallel economic assessments of innovative approaches. Barriers to economic analyses are well known: design and conduct of trials are already time consuming, complex, and costly; trials are concerned with establishing efficacy under ideal conditions, not effectiveness in community implementation; and trial costs may not reflect true-use costs because of market forces or excess monitoring and physicians' learning curve with a specific technology. Despite these concerns for pharmaceuticals, economic appraisals are increasingly required before approval by some governments and are being done prior to approval within managed-care organizations (1,2).

Drummond and Stoddart (3), in a landmark article, outlined the methodologic issues that arise in undertaking economic analysis alongside clinical trials. They proposed different criteria to determine the appropriateness of an economic assessment of a specific trial. In this article, I will focus on whether an economic assessment is indicated of the proposed phase III trial by the Eastern Cooperative Oncology Group (ECOG 5592) of etoposide and cisplatin versus paclitaxel (Taxol), cisplatin, and granulocyte colony-stimulating factor (G-CSF) versus paclitaxel and cisplatin in the treatment of advanced non-small-cell lung cancer, the new data requirements for such an analysis, and the issues of the incremental benefits of a "positive" trial.

The ECOG trial has straightforward entry criteria and design: patients had histologically confirmed stage IIIB or IV non-small-cell lung cancer and good performance status (ECOG  $\leq 1$ ). Specific exclusions were prior chemotherapy, biologic modifiers, radiation therapy, or active coronary artery disease. These patients were randomly assigned to receive one of the following investigation arms: high-dose paclitaxel with G-CSF plus cisplatin, low-dose paclitaxel plus cisplatin, or standard therapy (etoposide and cisplatin). Details of the drug dosing, monitoring, and dose-modification are discussed elsewhere (see the article by D. Johnson in this monograph). The primary end point is overall survival, with secondary end points of response rates and quality-of-life determinations.

## Should This Trial Have an Economic Assessment?

Table 1 lists factors to consider prior to initiating an economic assessment. The first major consideration is whether sizable amounts of resources are at stake. For this trial, this is the most compelling reason for an economic assessment. The trial addresses the most commonly fatal solid tumor; current therapies are not rapidly changing; the proposed therapy (paclitaxel) is readily transferable to the oncologist's chemotherapeutic armamentarium and, if safe and effective, would rapidly replace current approaches. The second consideration is whether the alternative strategies differ substantially in cost and/or morbidity (Table 2). Drug charges

**Table 1.** Factors supporting an economic analysis of a clinical trial

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Sizable amounts of resources are at stake
Common disease
Therapy is readily transferable to marketplace
Therapy will supersede, not supplement, other interventions
Alternative strategies differ substantially in cost and/or morbidity
Costs (e.g., standard drugs versus biotechnology)
Intervention (e.g., medication versus surgery)
Settings (e.g., prolonged hospitalization or invasive therapy)
Acute mortality (e.g., death due to surgery or transplantation)
Chronic morbidity (e.g., allo- versus auto-grafting for hematologic malignancies)

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**Table 2:** Cost and morbidity comparison of ECOG 5592 treatment arms

Factor	High-dose paclitaxel/G-CSF/ cisplatin versus cisplatin/etoposide	Low-dose paclitaxel/cisplatin versus cisplatin/etoposide
Drug cost	4+ (increased ~\$4000 per cycle)	2+ (increased ~2000 per cycle)
Invasiveness	No difference	No difference
Hospitalization and health-care encounters	Minimum 1 day hospital per course versus 3 outpatient days G-CSF $\times$ 10 days Febrile neutropenia	Same duration of hospitalization; no G-CSF
Acute mortality	"Toss-up"	"Toss-up"
Acute morbidity	2-3+ febrile neutropenia	1-2+ febrile neutropenia
Quality-of-life change	Benefit from increased response?	Benefit from increased response?
Likelihood of treatment delay	Not stated	Not stated

alone will be \$2000-\$4000 per cycle higher for the intervention arm than for the standard therapy (Medical College of Virginia hospital charges, March 1994). Since this is a comparison of chemotherapies, there is no difference in the invasiveness of each arm. The paclitaxel arms required a 1-day hospitalization and self-administered G-CSF (high-dose arm) compared with three outpatient treatments. The number of patient visits due to complications are not discussed in detail, but earlier experiences with paclitaxel suggest at least 70% of patients will have grade 3 or 4 neutropenia requiring additional monitoring. The risk of febrile neutropenia should be much greater for the paclitaxel arms. The acute mortality between these chemotherapies may differ, but is not as compelling a difference as in autologous transplantation or surgical trials. Whether differences in quality of life will appear is being assessed, since it is unclear if quality of life will be disproportionally improved because of a hoped-for greater response rate or decreased treatment as a result of associated toxic effects, infections, and paclitaxel neuropathy. Of these factors, the cost difference in the drugs, their delivery, and treatment for adverse effects is most compelling. The final consideration is whether the potential costs and adverse effects can be counterbalanced by a substantial benefit in the relevant end point. Since the trial's power calculation assumes only an increase in median survival of 6-9 months (a 50% increase), the absolute benefit is relatively small. Therefore, the case for an economic assessment of this trial is compelling.

### Is the Standard Approach the Community Standard?

A cornerstone question of either an efficacy or economic evaluation is whether the therapies evaluated reflect the real choices facing health care decision makers. For this trial, the initial question should be: Is etoposide and cisplatin for stage IIIB and IV lung cancer the standard approach? To definitely answer the question, this combination chemotherapy should improve life expectancy by a meaningful amount and be cost-effective compared with no therapy or best supportive care (BSC). Results to date are mixed. A recent review of chemotherapy in lung cancer stressed that, if there is a benefit, it is modest, and encouraged patients to participate in clinical trials (4). A more encouraging conclusion from a recent meta-analysis of chemotherapy trials compared with BSC showed

a small survival benefit (5,6). The only economic analysis of chemotherapy compared with BSC done retrospectively of a subsample of the Canadian BR-5 trial found that the more aggressive arm using cyclophosphamide, doxorubicin, and cisplatin was actually cost-saving compared with BSC and that vindesine and cisplatin compared with BSC had an incremental cost of about \$15 000 per year of life gained (1985 Canadian dollars). The cost differential was due to the greater late hospitalization and radiation use for the BSC arm (7). The impact of this finding on this trial will be discussed later. In conclusion, given the aggressive use of chemotherapy in the United States, etoposide and cisplatin reflect a commonly used treatment approach even if its rationality is not well established.

The ECOG trial highlights one of the first principles of cost-effectiveness analysis: the difference between average and incremental cost-effectiveness (8,9). Cost-effectiveness analysis begins with the presumption that resources are limited, and therefore it is not possible to undertake all measures that may extend life or improve its quality. Given a finite level of resources, cost-effectiveness analysis assumes that the goal is to maximize the aggregate health benefit, or, given a specific health effect, the goal is to minimize the cost of achieving it. This assumption assists policy makers in creating a rank-order list for setting funding priorities across competing programs. Average cost-effectiveness determines the cost per unit of benefit independent of alternative strategies. Incremental cost-effectiveness determines the additional costs to gain the additional benefits compared with the current approach. Therefore, for this trial, if the paclitaxel arms are more effective but more costly than the etoposide and cisplatin arm, then an assessment comparing the average cost-effectiveness of paclitaxel compared with BSC may be inappropriate. The correct analysis is to determine the incremental value added by paclitaxel, assuming that any chemotherapy is beneficial and prudent.

### New Data Requirements for Parallel Economic Analyses

If an economic analysis is performed in parallel with a clinical trial, the required collected data will expand (Table 3). Complications of therapy may or may not have major economic consequences. Modifications in dose and subsequent monitoring



by diagnostic testing for anticipated adverse effects (e.g., neutropenia and renal function) have relatively minimal economic effects. However, a greater rate of hospitalization for febrile neutropenia or sepsis dramatically increases the upfront costs of a given treatment arm. A less obvious requirement is expansion of the tracking of clinical care when the patient is taken off protocol. Most oncology trials stop following patients after confirmed disease progression, treatment toxicity, or patient refusal to continue therapy. Traditionally, the only additional and final data point is when death occurs. The ECOG 5592 protocol expands this to scheduled quality-of-life data even after treatment withdrawal. A prospective economic assessment cannot assume that the intensity and pattern of treatment after disease progression or withdrawal are similar for all treatment arms. This is the major lesson of the retrospective Canadian trial, which surprisingly found that BCS had higher total hospitalizations. If detailed monitoring is not feasible, then off-protocol scheduled collection of major known cost categories should be tracked. For this trial, a suggested off-protocol dataset includes hospital days, indication for hospitalization, indication for radiation therapy and number of radiation treatments, number and type of palliative chemotherapy treatments, and hospice-care days.

An even more problematic design issue is if the protocol should dictate subsequent forms of palliative care. For example, is late or salvage use of one of the initial treatment protocol agents (e.g., paclitaxel) allowed? Such restrictions could reduce patient accrual by limiting returning patients to community care and its associated practice patterns. The other issues in Table 3 are discussed in more detail in other articles in this monograph.

The need for economic analysis prior to the adoption and use of new technologies or pharmaceuticals is compelling. The quality and sophistication of the economic analysis need improvement (10,11). Many of the principles of critical appraisal, evidence-based medicine, and development of clinical practice guidelines overlap and are dependent on sound first principles of clinical and economic trial design. Table 4 provides a checklist of factors, distilled from various sources, for designing and reporting economic analysis (10,12). If the additional cost is 15%-25% to add an economic assessment of ECOG 5592, I expect that from a health-policy perspective, it will be money well spent.

**Table 3.** New data requirements for parallel economic analyses

Tracking of costs for treatment complications
Tracking of costs beyond treatment failure (disease progression, study withdrawal)
Statistical estimate and power calculation of meaningful cost differences
Most, if not all, centers and patients participate in economic analysis
Identification of protocol-specific induced costs
Identification of resources used (true costs) compared with charges
Expansion of quality-of-life assessment to measurement of patient utilities

**Table 4:** Checklist for economic analyses

Is a current community standard of care established?
Statement of type of analysis (cost-benefit, cost-effectiveness, or cost-minimization)
Viewpoint explicitly stated (societal, payer, provider, or patient)
Statement of type and completeness of economic analysis
Appropriate determination of incremental benefits
Definition of direct costs measured
Appropriate determination of incremental costs
Distribution pattern of costs and benefits
Discounting
Sensitivity analysis

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# Prostate Intervention Versus Observation Trial (PIVOT): a Randomized Trial Comparing Radical Prostatectomy With Palliative Expectant Management for Treatment of Clinically Localized Prostate Cancer

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*For the PIVOT Planning Committee*

Prostate cancer is now the most common non-skin cancer diagnosed in humans in the United States. The American Cancer Society estimates that, for 1994, 200 000 new cases of prostate cancer were diagnosed in the United States, with 38 000 deaths (1). This mortality rate ranks second behind that for lung cancer, but ahead of that for colon cancer. In 1973, for comparison, 38 000 men were diagnosed with prostate cancer, with 18 000 deaths (2). Thus, during the past 20 years, the rates of death from prostate cancer have more than doubled from 18 000 to 38 000 deaths per year, while the diagnosis rate has risen sixfold from 38 000 to 200 000 cases per year. One might conclude from these data that prostate cancer has become "epidemic" but that it is being successfully treated as shown by the proportionately slower growth in mortality rates. An alternative hypothesis is that prostate cancer is often indolent and that most patients die before the cancer is able to spread and/or acquire an aggressive phenotype and to become the cause of death. In keeping with this latter hypothesis, step-section histologic studies have demonstrated that at least 30% of men older than age 50 years have a focus of prostate cancer (3). In a U.S. population of approximately 30 million men older than age 50 years (4), 9 million men would have histologic prostate cancer. Thus, it is obvious from these figures that, while prostate cancer is a major cause of death, the majority of men die *with* their cancer rather than *of* it.

When one evaluates patterns of treatment of prostate cancer in Europe compared with those in the United States, there are marked differences. The European physicians take a much more passive clinical approach toward therapy, often waiting for metastatic disease to develop before initiating palliative treatment. Several authors, notably Johansson et al. (5) from Sweden, have suggested that survival rates for patients treated conservatively (5-9) are similar to those for more aggressively (surgically) treated men in the United States (9-16).

Although these results raise some questions as to how often prostate cancer is potentially curable, a fundamental dilemma is related to competing influences. Prostate cancer generally grows slowly and is diagnosed in older men. Thus, deaths from non-

prostate cancer causes are common. As a broad estimate, the 15-year survival of men in this age group is about 50%. A second confounding factor is that of tumor grade. It has generally been accepted that tumors of low grade are less likely to progress clinically. However, analysis of the conservative-treatment trials shows a mean age at entry of 70 years, with about half of the patients having grade 1 tumors (17). These factors will tend to limit identification of any possible benefit from interventional therapy, leading to the conclusion that watchful waiting is the appropriate course of action. In addition, the study by Johansson et al. (5) revealed a relatively low 10-year survival rate, possibly exaggerating the competing causes of death. In another study, a meta-analysis was performed on 828 nonrandomly allocated, conservatively treated patients from six centers in the United States and Europe (18). This study concluded that, for men with grade 1 or 2 tumors (19) and less than a 10-year life expectancy, conservative therapy and delayed hormonal treatment were reasonable options, though the reservations regarding individual studies apply also to the combined data.

A study in 1993 (20) utilized the Markov model method to evaluate the benefits of active intervention over watchful waiting. The Markov model is a decision-analysis model in which patients may fall into one of several disease states (e.g., no evidence of disease or alive with disease). The model then allows patients to move from one health state to another over an extended period. Available clinical data are used to input the model and provide a basis for transition rates from one disease state to another. Likewise, complication data (e.g., incontinence or impotence after treatment) are used to provide a basis for quality-of-life calculations. However, the negative impact on

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See "Note" section following "References."

quality of life (patient utilities) for these items may have a dramatic effect on quality-of-life "years saved" as a result of therapeutic interventions, and these patient utilities are assigned arbitrarily by the investigators. With these theoretical limitations, the study conclusion was that, on average, curative treatment resulted in less than a 1-year improvement in quality of life and adjusted life expectancy.

Patterns of care within the United States vary widely, with the northeastern part of the United States (e.g., Rhode Island and New York) having a relatively low rate of radical prostatectomy compared with other areas of the United States such as the Pacific Northwest (e.g., Washington and Alaska), where surgery rates are more than six times higher (Table 1) (21). During the period 1984-1988, the incidence rate of prostate cancer increased 25%, while the radical prostatectomy rate increased 250% (21).

The American Cancer Society and the American Urological Association now recommend annual screening with digital rectal examination and prostate-specific antigen (PSA) determination for men older than age 50 years or men older than age 40 years if risk factors exist, such as family history of prostate cancer or African-American ethnicity. A cost analysis published in 1990 (22) concluded that screening the whole population in this manner would utilize \$27.9 billion annually, at a time when annual spending for prostate cancer was \$255 million (based on pre-PSA incidence rates), a change in total health care allocation from 0.06% to 5%.

The above data demonstrate a very confusing picture that is nicely summarized by the following widely quoted dictum of Whitmore (23): "If treatment is possible is it necessary, and if necessary is it possible?" Reflecting this paradox, prostate cancer is the leading cause of cancer death yet, relative to its histologic frequency, rarely causes death. Single-arm, nonrandomized experiences demonstrate similar rates of survival regardless of whether or not treatment was given. Analysis of these series demonstrates differences in the populations, making true comparisons impossible. It has therefore been evident to urologists (at a theoretical level) that a need exists for a randomized study in which different forms of treatment are directly compared. It has also been recognized by urologists and epidemiologists that active treatment programs are very expensive, though this aspect has not really entered into protocol development. From this position of clinical uncertainty was developed the Prostate Intervention Versus Observation Trial (PIVOT).

## Purpose of PIVOT

The essential question to be answered by this trial is as follows: Does maximal intervention for the treatment of localized prostate cancer significantly reduce all-cause mortality rates compared with palliative therapy? For maximal intervention, radical prostatectomy was chosen over other forms of therapy on the basis of the assumption that, while other forms of therapy may arguably be offered as equivalent to surgery, there is not much challenge that they are medically superior. To test several different modalities of maximal therapy, all within the same single arm, would lead to unassessable data, and a three-arm study (adding radiation therapy) would have massively in-

**Table 1.** Radical prostatectomy rates per 100 000 for Medicare beneficiaries (1988-1990)

State	Rate
Rhode Island	20
New York	50
Washington	327
Alaska	429

creased the enrollment requirements and would have complicated already difficult patient enrollment criteria.

The primary outcome measure to be determined is all-cause mortality. The rationale for this end point is twofold: 1) All-cause mortality is unbiased and is an easily defined end point. 2) In the final analysis, the performance of radical prostatectomy is based on the belief that surgical extirpation not only will cure the disease but also will prolong the patient's life.

The secondary end points to be studied are as follows: 1) prostate cancer-specific mortality; 2) effects on health status—the prostate cancer-specific quality-of-life scale of the Southwest Oncology Group, the symptom index and bother scores of the American Urological Association, and the SF-36 general health status questionnaire to be used to determine which of the two treatment approaches provides superior quality of life; 3) effect on disease recurrence; 4) progression-free survival; 5) a serum and tissue bank to be established for future studies using techniques not currently available; 6) demographic data to be collected on (a) race, (b) age, (c) tumor stage, (d) tumor grade, (e) tumor volume, (f) family history of prostate cancer, (g) PSA level and rate of change of PSA level, and (h) Charlson comorbidity index in order to predict all cause- and cancer-specific mortality.

## Patient Eligibility for PIVOT

To be eligible, patients have to be 75 years of age or younger with at least a 10-year life expectancy. In addition, they have to have clinically localized prostate cancer of T1a,b,c, T2a,b,c, and Nx and Mo, and their prostate cancer must have been diagnosed within the preceding 6 months.

In order to assess how representative the randomly allocated patients are of prostatectomy-eligible patients as a group, information on all patients seen at each institution with newly diagnosed prostate cancer will be logged into the database. Ultimately, it may be possible to draw some conclusions as to how randomly allocated patients may or may not reflect the experience of patients nonrandomly electing either aggressive or conservative treatment approaches.

Patients are excluded for the following reasons: 1) life expectancy less than 10 years or condition placing the patient at unacceptable surgical risk (e.g., myocardial infarction within the last 6 months), 2) prior treatment (except transurethral resection of the prostate) for prostate cancer, and 3) evidence of metastatic disease.



## Statistics

The study will enroll 2000 patients over a 3-year period and then will follow them for an additional 12 years, giving a total study duration of 15 years. This number is anticipated to provide a 90% power to detect a reduction in the all-cause mortality rate of 15% and assumes a potential type 1 error of 5%.

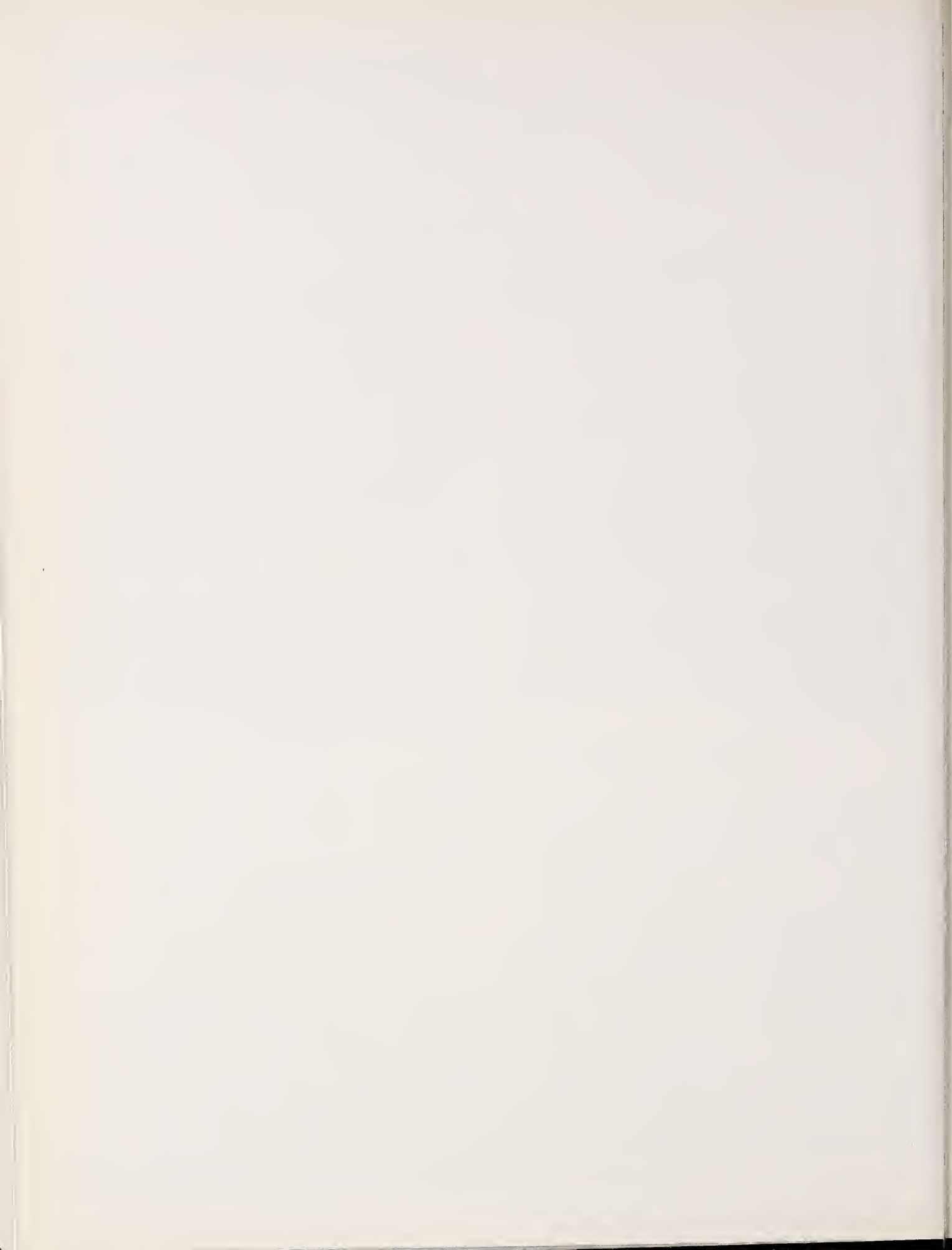
These statistical numbers were based on the following two observations: 1) The best estimated median survival on expectant therapy is 15 years, and 2) the age cutoff for patient entry was chosen to provide a liberal approach to patients having a 10-year survival expectation. While life tables place this 10-year survival at slightly less than 74 years of age, patient eligibility should make patients with prostate cancer slightly better than average (hence, the choice of 75 years).

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# Prostate Cancer Intervention Versus Observation Trial: Economic Analysis in Study Design and Conditions of Uncertainty

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The Prostate Cancer Intervention Versus Observation Trial (PIVOT) compares radical prostatectomy with palliative expectant management of patients with clinically localized prostate disease. As with all clinical trials, several of the assumptions underlying PIVOT are characterized by uncertainty. Economic analysis has the potential to clarify some of these important issues, thereby guiding study design and interpretation and enhancing the clinical usefulness of the findings. One important uncertainty about the trial relates to the true clinical state of potentially eligible patients. While clinical examination is an insensitive method by which to stage prostate cancer, several diagnostic tests, such as bone scanning and magnetic resonance imaging with rectal coil, are more accurate but more expensive. Another issue is whether to start the trial with the screening of patients or at the time of prostate cancer diagnosis. Economic analysis can assess these trade-offs between study cost and validity. A second potential role for health economics is in dealing with the considerable uncertainty surrounding the study's findings and conclusions and their interpretation. While the stated primary outcome of the trial is survival, a multi-dimensional outcome (particularly one that incorporates factors of survival, quality of life, and cost) is likely to be more clinically relevant in the prostate cancer population, given the only modest improvements in survival hypothesized for radical prostatectomy. To develop such a measure, quantitative assessment of patient preferences is required, in addition to the measures currently included in the study. Assessment of costs of care are important, given the large and growing size of the study's target population. However, assessment of economic costs is problematic, given PIVOT's protocol-induced costs, the need to incorporate discounting to account for the time effects of costs and benefits that accrue differentially, potential problems with generalizability of the results to the clinically relevant population, and the impact that an economic end point may have on study sample size. [Monogr Natl Cancer Inst 19:73-75, 1995]

The proposed randomized Prostate Cancer Intervention Versus Observation Trial (PIVOT) comparing radical prostatectomy and palliative expectant management of men with clinically localized prostate disease is characterized by an unusual amount of uncertainty regarding a variety of study assumptions. Economic analysis has the potential to clarify some of these impor-

tant issues and thereby guide both the design of the study and the interpretation and clinical usefulness of the findings. In particular, health economics may contribute to improved study design and planning, improved outcome measurement, and improved interpretation and application of study results.

## Study Planning

One potential and underutilized role for health economics is to enhance study planning and design. In all clinical studies, resources are limited and constrain the questions that can be addressed. Choices, therefore, must be made about which questions to address; there are trade-offs among study design, methodologic rigor, generalizability of results, cost, statistical power, and resources.

A study's sample size is a function of several factors, including the benefits to be detected and their frequency in the population studied, the population at risk, and the ability to implement the trial. Because study size affects the level of detectable risk reduction, the expectant risk reduction will drive the sample size and the sample size will determine the change in outcome measurable if the intervention is effective.

Cost is another function of sample size. The larger the population studied, the more the trial costs. There is also a relationship between the value of the detectable benefits and the cost. Thus, in planning a trial, there are inherent trade-offs between the cost of the trial and the ability to detect the effectiveness of the intervention; all of these can be quantified using standard economic methods.

In PIVOT, considerable uncertainty surrounds the true clinical state of potentially eligible patients. In particular, prostate cancer staging to determine study eligibility is determined by clinical examination. Yet, it is well known that clinical examination is an insensitive method to stage prostate cancer. The study investigators estimate that as many as 30% of patients determined by clinical examination to have localized cancer and entered in the study will actually have extracapsular disease. Several diagnostic tests, such as bone and computed tomographic scans, can stage prostate cancer more accurately than clinical examination. Body magnetic resonance imaging supple-

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mented with a rectal coil may be the most sensitive currently available method for the staging of prostate cancer.

Two factors may have mitigated against the use of more sensitive diagnostic tests to stage prostate cancer in potentially eligible patients. The investigators want to conduct a study that parallels current clinical practice as much as possible to enhance the generalizability of the results. However, the results of the trial will not be available for up to 15 years, and by then it is almost certain that more accurate means to stage prostate cancer will be commonly employed in practice.

The use of diagnostic tests to stage prostate cancer in potentially eligible patients also increases study costs, in the short term, by increasing the number of patients who need to be screened for study inclusion and by the need to perform the staging test on all potentially eligible patients. However, this perspective overlooks the fact that inclusion of patients who do not have localized disease incurs full study costs and actually confounds efforts to answer the study question, increasing the sample size required and increasing the complexity of interpreting study results. Thus, enhanced staging of potentially eligible subjects may actually reduce study costs by excluding patients with advanced disease who cannot benefit from the intervention.

A common challenge in designing clinical trials is to decide whether the increased diagnostic accuracy and the resultant improvement in the construction of the study cohort is worth the additional cost incurred. The only way to address this issue is through the use of economic modeling. Specifically, one needs to estimate the increased cost resulting from performing the staging test on all potential study patients. This figure then must be compared with the costs saved by reducing the number of patients with nonlocalized disease entered in the study. These patients incur full study costs without contributing useful information. In PIVOT, the false-negative rate of clinical staging is sufficiently high that even modest improvements in prostate cancer staging will actually reduce study costs while increasing the statistical power and simplify the study logistics.

## Functional Outcome Measurement

PIVOT is characterized by the considerable amount of uncertainty that will surround the study's findings, conclusions, and interpretation. Although the trial's stated primary outcome measure is survival, the investigators postulate only modest (if any) increases in survival from the use of radical prostatectomy compared with watchful waiting and more conservative palliative therapy. Thus, outcomes that focus on factors other than survival, such as quality of life and cost, are likely to be more clinically and policy relevant.

Quality of life and functional status are multidimensional in nature. There are a variety of functional status and quality-of-life measures in which physicians, patients, and family members will be interested, including cognition, emotional and psychological status, pain, ability to engage in activities of daily living and work and other routine social activities, impotence, libido, incontinence, and general well-being. Alternative prostate cancer therapeutic interventions will impact differentially among these parameters. For example, radical prostatectomy may result in a few months of increased survival, but at the cost of in-

creased sexual dysfunction and recurrent urinary tract complications. Thus, a broad range of functional status outcomes must be measured, especially for prostate cancer, where an intervention's impact on functional status and quality of life may dominate patient choices and preferences.

Since patients differ in their preferences for outcomes, optimal therapy may well differ among patients. There may not be one standard of care that is appropriate for every patient. Rather, choice of therapy may well be a function of patient acceptance of particular complications and reductions in functional status relative to potential enhanced survival. Thus, patient preferences and utilities for relevant functional states, complications, and outcomes must be assessed in a rigorous, valid, and reliable fashion. Furthermore, a mechanism is needed to quantitatively weigh and integrate these various outcomes to maximize the applicability and value of the study findings for individual patients and physicians.

## Cost-Effectiveness

As noted above, if radical prostatectomy is more effective than conservative therapy, any such improvements are likely to be modest at best and likely to be mixed (an increase in some outcomes and a reduction in others) and achieved at some increased cost. In such a situation, the practical clinical and policy issue will be to quantify the trade-offs between increased cost and improved effectiveness in order to guide therapy. This is best assessed by conducting an incremental cost-effectiveness analysis of PIVOT interventions, comparing the additional cost of the intervention with its additional benefit. Given the various clinically relevant and policy-relevant outcomes of interest in this trial, either a series of incremental cost-effectiveness analyses using a variety of outcomes or a method to synthesize the findings in an integrative fashion, such as "quality-adjusted life years" or other utility assessment measures, will be required.

Assessment of the costs of care is important, given the large and growing size of the study's target population. Assessment of economic costs in PIVOT, however, is complex and problematic. Inherent in the study are protocol-induced costs—costs dictated by adherence to the study requirements. Protocol-induced costs may either increase or decrease the costs that would be incurred in normal practice. Increased costs result when otherwise unnecessary services are performed as a result of being dictated by the protocol.

Protocol-induced costs result in lower costs than would be incurred in routine practice when services required by the protocol detect ineffective interventions or complications and adverse events at an earlier stage than would otherwise have occurred; corrective intervention is instituted when it is more effective and forestalls larger costs in the future.

The impact of protocol-induced costs on the alternative interventions is asymmetric. Excess costs often are incurred by the more effective therapy as a result of otherwise unnecessary services dictated by the protocol. Conversely, costs incurred by the less effective therapy are often underestimated as a result of avoiding services that subsequently might have been necessary. Thus, protocol-induced costs often act to reduce the difference in costs between interventions.



Another problem in assessing the costs in PIVOT relates to the differential time course of the costs and benefits of the alternative interventions. In PIVOT, substantial economic costs, mortality, and complications will be incurred early in the trial as a result of radical prostatectomy. Potential financial and health benefits will occur at a later point in the trial. Thus, there is a need to incorporate discounting to factor in the time effects of costs and benefits.

These economic assessments have a significant impact on important aspects of the study design, including sample size. Economic assessment of alternative methods of prostate cancer staging may result in a need for a smaller study sample as a result of greater staging precision. On the other hand, assessment of the incremental cost-effectiveness of the alternative interventions may require a larger sample size than the clinical outcomes to adequately answer the study question. Failure to incorporate this consideration into study planning may result in a study that does not provide sufficient precision to guide clinical practice and policy recommendations and decisions.

Finally, despite the intuitive attraction of a simple and straightforward statistical measure of significance of the primary and secondary outcome measures, even after completion of this study, there is likely to be substantial uncertainty and controversy surrounding the findings. This is true because of the various assumptions and study design decisions required by the trial and any resulting significant trade-offs among the various outcome measures.

The complexity, cost, and time requirements of such a trial preclude additional studies to verify and confirm the results. In such a situation, decision-modeling techniques will be required to integrate the PIVOT data, to assess the impact of the considerable variability and uncertainty in the data, to specify trade-offs among alternative strategies, to bound the estimates of the likely ranges of interpretation of the results, to identify optimal management strategies, to update these optimal strategies as new data become available, and to identify priorities for future research.





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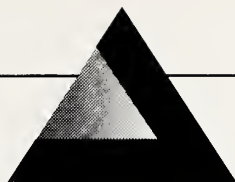
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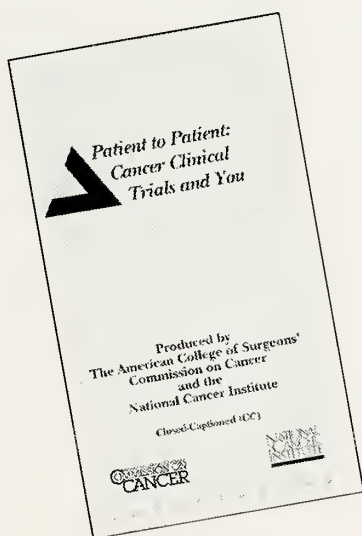
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